Attachment 1

NRDC Stands with Those Calling for Racial Justice

NRDC

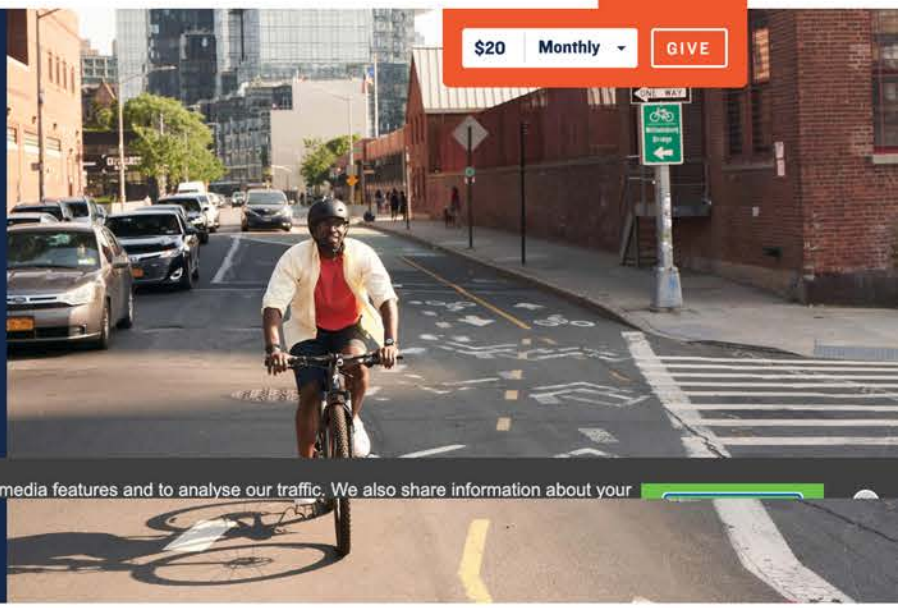
OUR WORK OUR EXPERTS OUR STORIES GET INVOLVED ABOUT US DONATE

$20 Monthly GIVE

BE A FORCE FOR THE FUTURE

Defending our air, water, communities, and wild places requires more than a single voice. Join the movement.

+ JOIN US



Since 1970

NRDC has worked to ensure the rights of all people to clean air, clean water, and healthy communities.

LEARN MORE →

Don't let Trump use the COVID-19 crisis to roll back public health protections

TAKE ACTION

Stop the Trump EPA's assaults on science and safeguards

TAKE ACTION

BATTLING URGENT THREATS

We combine the expertise of some 700 scientists, lawyers, and advocates with the power of more than three million members and online activists to confront our planet's most pressing problems.

NRDC Responds to COVID-19

This unprecedented public health crisis requires bold, equitable, science-based action.

Trump Takes Moment of National Crisis to Give Polluters an Unprecedented Pass

Amid widespread racist violence and a deadly pandemic, the president has chosen to sidestep bedrock environmental laws that protect the environment and public health.

Confronting Racism and Brutality with Justice and Truth

The arc of the moral universe may bend toward justice, but only if we bend it that way.

BUILDING A BETTER FUTURE

Help us safeguard the air we breathe, the water we drink, and the places we treasure.

$10 $12 $15 $18 $20 $

ONE-TIME GIFT GIVE MONTHLY

DONATE

EARTH'S BEST DEFENSE

We focus on fundamental issues in order to protect the natural systems on which all life depends.

CLIMATE CHANGE COMMUNITIES ENERGY FOOD HEALTH

OCEANS WATER THE WILD

A LEGACY OF IMPACT

NRDC has helped pass our nation's bedrock environmental laws. We continue to ensure those laws are enforced and polluters are held accountable.

LEARN MORE →

38K SQUARE MILES OF MID-ATLANTIC OCEAN WATERS PROTECTED

5 TONS OF MERCURY FROM DENTAL OFFICES KEPT OUT OF OUR WATER

$97M LEGAL SETTLEMENT TO EXAMINE AND REPLACE WATER LINES IN FLINT

3M TONS OF WATER CONSERVED THROUGH NRDC'S CLEAN BY DESIGN PROGRAM

18 YEARS FIGHTING TO REVIVE THE SAN JOAQUIN RIVER AND THE FISH AND JOBS IT CAN SUPPORT

5 TURBINES CHURNING IN THE FIRST U.S. OFFSHORE WIND FARM NEAR BLOCK ISLAND

42 PERCENT OF THE U.S. CHICKEN INDUSTRY COMMITTED TO RESPONSIBLE ANTIBIOTICS PRACTICES

LOCAL FIGHTS

Whether in California or Chicago, India or Canada, we help protect communities around the world using decades of legal, scientific, and policy expertise.

BLOG POST

Energy Efficiency Can Help Us Emerge from the Pandemic

Energy-saving programs can help make buildings healthier while lowering electric and gas bills—freeing up much-needed cash that can be used for food, rent, and medicine, and by municipalities for things like fire stations and schools.

NRDC IN ACTION

These NRDC Experts Show Us How We Can Slow the Spread of Zoonotic Diseases

It will take the highest levels of international cooperation, but by working to curb wildlife trade and conserve vast swaths of disappearing habitat, we can minimize the interspecies interactions that spread viruses.

BLOG POST

Court Deals Another Blow to Keystone XL, Invalidates Key Permit

Siding with NRDC and our partners, a federal court agreed that the Nationwide Permit 12 allows dangerous pipeline projects to skirt environmental laws.

SUPPORT OUR WORK

$35 $50 $75 $100 $200 OTHER DONATE

JOIN US

Enter Email SUBMIT

When you sign up you'll become a member of NRDC's Activist Network. We will keep you informed with the latest alerts and progress reports.

NRDC

ABOUT US
CAREERS
CONTACT US
MEDIA CENTER

POLICY LIBRARY
SITEMAP
EN ESPAÑOL
PRIVACY POLICY

FOLLOW US

Attachment 2

Telfer, Kathleen

From: NRDC - Rhea Suh <alerts@nrdcaction.org>
Sent: Thursday, September 14, 2017 4:15 PM
To: Telfer, Kathleen
Subject: Pruitt doesn't want to talk climate -- so we will

Dear Kathleen–

The science indicates that Hurricanes Irma and Harvey were almost certainly made more powerful and destructive by climate change. These storms, along with the record heat and raging wildfires in the West, are calling out for real solutions to climate change.

EPA chief Scott Pruitt says he doesn't believe we should be talking about climate change now. No surprise, given Pruitt's and President Trump's climate denial and their efforts to roll back climate action.

But attitudes are shifting — including among Republicans. As Tomás Regalado, Republican mayor of Miami, FL — a city battered by Irma — countered: *"This is the time that the president and the EPA and whoever makes decisions needs to talk about climate change."*

And Senator John McCain told CNN this week that it was time to sit down and discuss potential solutions to climate change.

Let's use Mayor Regalado's and Senator McCain's bipartisan call to arms to pressure Democrats and Republicans to renounce climate denial and embrace climate action. ***Take action or find out more below.***

Thanks for your support.

Kathleen,

It's been 11 days since Hurricane Harvey struck Texas, and now many Caribbean islands and Florida and other southeastern states face a new potentially devastating hurricane with Irma.

The nation is focused — as we should be — on recovery and rebuilding in the wake of Harvey, and all-important preparations for this new storm racing toward us.

But looming large over these storms is an issue that we ignore at our own peril: climate change.

No climate scientist would pin all the blame for any one hurricane or any one extreme weather event on climate change.

With Harvey and Irma, Help Turn Disaster Into Climate Action

Send leaders a last-chance wake-up call: Hurricanes Harvey and Irma are a turning point in America's fight for climate solutions.

TAKE ACTION

But we do know this: climate change almost certainly made Harvey more devastating. The Gulf of Mexico's waters are at record warmth. And warmer waters and air fuel more powerful and destructive storms.

Only the willfully blind can ignore the larger pattern of extreme weather: Harvey is the third 500-year storm — or worse — to hit Houston in just three years. It is just the latest in a string of catastrophic floods and storm events to strike the nation. Across America and around the world heat waves and rainstorms are growing more intense — just as climate scientists have predicted for decades.

At this point, climate change is *screaming* for our attention. But President Trump and congressional leaders have got their fingers in their ears, pretending that all will be well if only we would agree to deny climate science.

That aversion to science is looking more and more like an invitation to a rolling planet-wide catastrophe. We've seen the future and it looks a lot like Houston.

So, please send our leaders a wake-up call: Hurricanes Harvey and Irma must be

the turning point in America's willingness to tackle climate change and aggressively pursue a clean energy future.

We'll send your message to President Trump, Vice President Pence, cabinet officials, Congress, and your governor and state representatives, all of whom must act now and must know that we are watching them.

The fossil fuel industry still has a financial stranglehold on far too many politicians. Here's the evidence:

- President Trump's proposed federal budget — which is now being negotiated by Congress — seeks to abolish nearly every climate change program on the books at the EPA, Department of Energy, and other key agencies.
- Agency officials like the EPA's Scott Pruitt are ignoring — or driving out — scientists we urgently need working on climate change and clean energy.
- The Trump administration is pulling America out of the Paris climate agreement and trying to dismantle the Clean Power Plan — our single best hope for speeding up the transition away from coal and other dirty fossil fuels.
- And the administration is ramping up efforts to drill for more oil and gas in the Arctic, off our coasts, and even in our cherished national monuments.

These attacks must stop, and after Hurricane Harvey, **we must demand that President Trump, Congress, and even state and local leaders get serious about tackling climate change before it's too late**.

But make no mistake: we must do *more* than cut global warming pollution. Burning of fossil fuels has already locked us into more climate change — *and more extreme weather*. **So it's absolutely crucial that, in the wake of Hurricane Harvey and with Irma approaching, we clean up and rebuild in a way that protects millions of people in vulnerable areas from future storms.**

That's why NRDC and the NRDC Action Fund are working closely with our partners in the Gulf region and around the country to address the recurring problems of flooding from record storms and sea level rise ... the toxic mess left behind by flooded petrochemical plants ... fighting back in Washington against short-sighted cuts to FEMA, the National Weather Service, NOAA, and other agencies that better prepare us for the impacts of climate change.

And right now, we are pushing to fix the fatally flawed federal flood insurance

program that continues to subsidize building in flood-prone areas. And we're working to reverse President Trump's decision, just days before Harvey hit, to abolish federal flood standards meant to protect people and property from storms like this.

In the days and weeks ahead, we will call on members and supporters like you to ratchet up the pressure on political leaders to abandon policies that are making natural disasters like Hurricane Harvey even worse, and to win new, smarter policies that will better protect all Americans.

But for now, please seize this moment to send a message demanding strong action on climate — for the sake of every person on this planet.

Sincerely,

Rhea Suh
President, NRDC

The mission of the Natural Resources Defense Council (NRDC) is to safeguard the Earth: its people, its plants and animals, and the natural systems on which all life depends.

Attachment 3

ACT NOW

Whether you want to fight against Big Coal
will make a difference.

FILTER BY...

-- All options --

Tell Trump and the EPA to drop their attacks on clean car standards

TAKE ACTION →

Tell Congress to save our national monuments

TAKE ACTION →

Stop the Trump administration's offshore drilling assault

TAKE ACTION →

Stop Trump's pro-polluter push to throw out environmental reviews

TAKE ACTION →

Tell the EPA to drop its disastrous assault on clean air protections

TAKE ACTION →

Stop the Pebble Mine and protect Alaska's wilderness

TAKE ACTION →

Demand that Trump protect public health, not polluter profits

TAKE ACTION →

Protect our public lands from Trump's attacks

TAKE ACTION →

Tell Bayer-Monsanto to stop selling bee-killing neonic pesticides

TAKE ACTION →

1 2 3 4 5 6 7 8 9 NEXT › LAST »

SUPPORT OUR WORK

$35 $50 $75 $100 $200 OTHER DONATE

JOIN US

Enter Email SUBMIT

When you sign up you'll become a member of NRDC's Activist Network. We will keep you informed with the latest alerts and progress reports.

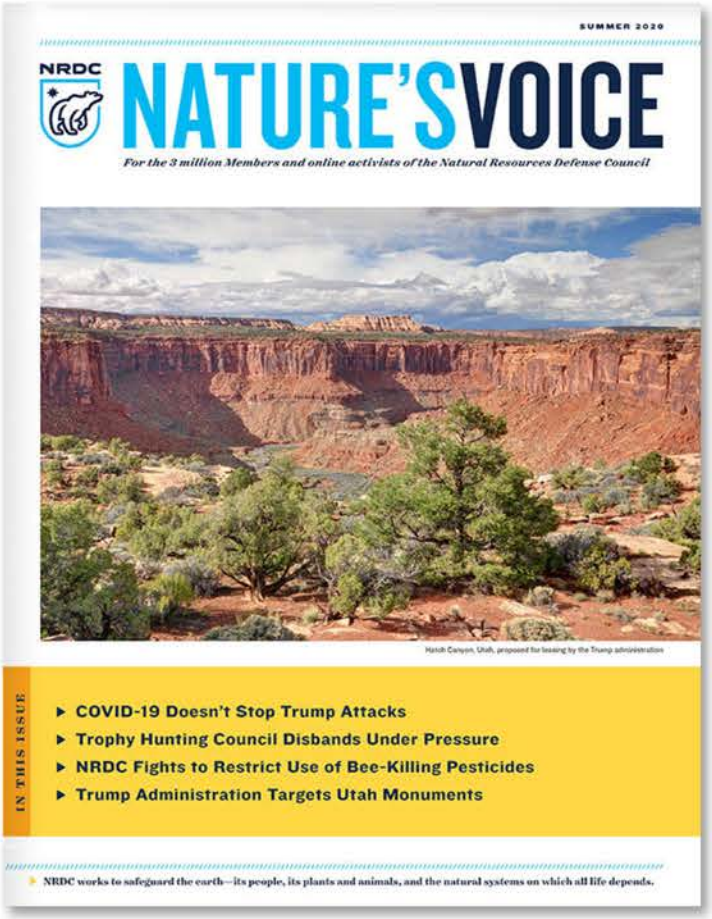
NRDC

Attachment 4

Nature's Voice

Share

CURRENT ISSUE: Summer 2020



READ ISSUE

In This Issue


COVID-19 Doesn't Stop Trump Attacks


Trophy Hunting Council Disbands Under Pressure


NRDC Fights to Restrict Use of Bee-Killing Pesticides

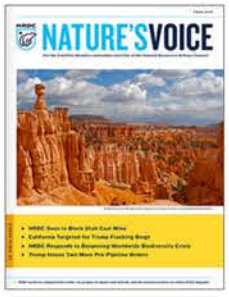

Trump Administration Targets Utah Monuments

Past Issues

See more issues →

Spring 2020

Winter 2020

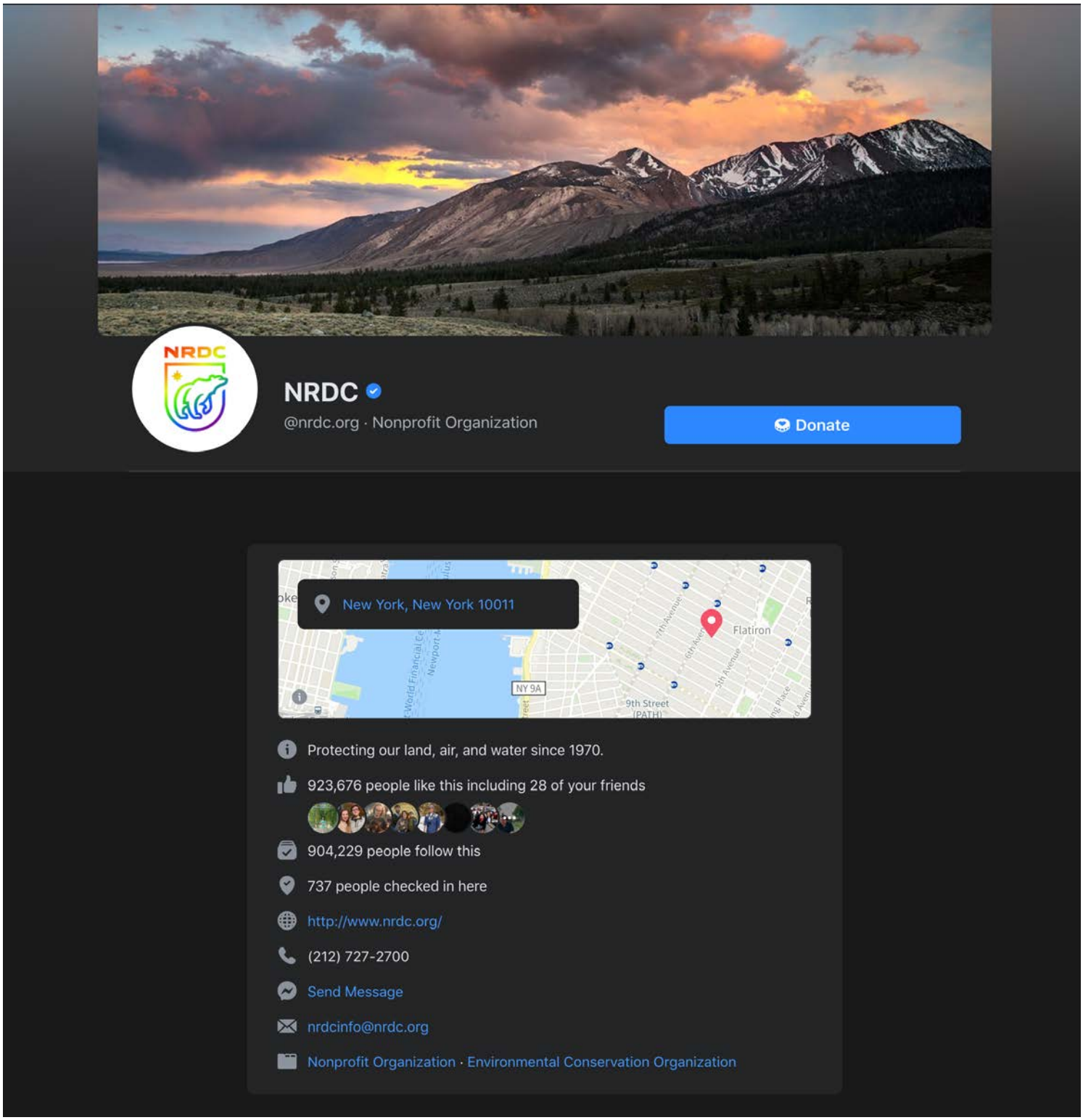


Fall 2019

Join NRDC for as little as $15 and help us wage and win our campaigns in defense of wildlife and wild places. You will automatically receive *Nature's Voice* in the mail 4 times per year.

JOIN NOW

Attachment 5


NRDC
NRDC
@nrdc.org · Nonprofit Organization
Donate
New York, New York 10011
Flatiron
NY 9A
9th Street
(PATH)
Protecting our land, air, and water since 1970.
923,676 people like this including 28 of your friends
904,229 people follow this
737 people checked in here
http://www.nrdc.org/
(212) 727-2700
Send Message
nrdcinfo@nrdc.org
Nonprofit Organization · Environmental Conservation Organization

Attachment 6

NRDC
94K Tweets

Follow

NRDC
@NRDC

NRDC (Natural Resources Defense Council)
The Earth's Best Defense

Planet Earth · nrdc.org · Born January 1, 1970 · Joined January 2009

3,674 Following **336.4K** Followers

Followed by Northern Plains, Yes on 67, and 8 others you follow

Tweets | Tweets & replies | Media | Likes

Pinned Tweet

NRDC @NRDC · Jun 30

#SolvingTheClimateCrisis means building a clean energy economy with #EnvironmentalJustice at its foundation. The @ClimateCrisis Committee just released their Action Plan to set up a healthy future. Here are some ways we must #ActOnClimate: [THREAD]

1 · 16 · 28

Show this thread

NRDC Retweeted

NRDC Gov't Affairs @NRDCFedGov · 16m

Lead in drinking water is never safe, but 9 million homes get water from lead service lines—and Black & Brown communities face disproportionate amounts. Thank you @RepChuyGarcia for working to ensure the #MovingForward Act will #GetTheLeadOut! #ProtectCleanWater

> **Congressman Chuy García** @RepChuyGarcia · 1h
>
> .@RepPressley and I have an amendment in the #MovingForwardAct which directs @HUDgov to provide grants to remove lead pipes in our nation's public and federally assisted housing.
>
> It's past time for Congress to keep families safe and healthy in their homes.

13 · 19

NRDC @NRDC · 37m

Another example of environmental racism? America's lead in drinking water crisis. Dr. @monahannaa, a pediatrician who helped expose the lead water crisis in Flint, Michigan, talks about why we must protect children from this toxic metal: on.nrdc.org/314HZYD

Search Twitter

You might like

Yale Environment ... @YaleE360 — Follow

Climate Desk @ClimateDesk — Follow

UN Environment P... — Follow

Attachment 7

Instagram

Search

nrdc_org Message

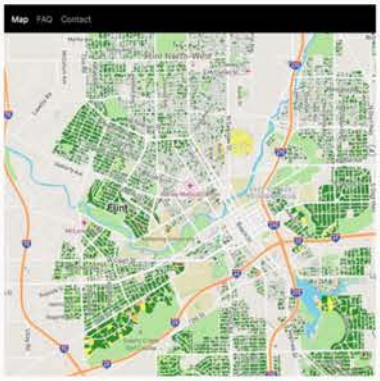
2,246 posts 289k followers 736 following

NRDC
Nonprofit Organization
NRDC (Natural Resources Defense Council)
The Earth's Best Defense
likeshop.me/nrdc_org

Followed by livingwithoilandgas, austyngaffney, patagonia + 4 more

General ... Chicago EJ BLM Agriculture APAHM Trivia Tues... Trivia Tues...

POSTS IGTV TAGGED



Attachment 8

YouTube

Search

Home

Trending

Subscriptions

Library

NRDC

NRDCflix

23.3K subscribers

SUBSCRIBE

HOME VIDEOS PLAYLISTS COMMUNITY CHANNELS ABOUT

The NRDC Story

45,439 views • 5 years ago

The Natural Resources Defense Council was founded in 1970 to protect our air, land, and water from the forces of pollution and corporate greed. We protect. We defend. We lead the way. Join us: www.nrdc.org.

Drawing Out The Science

▶ PLAY ALL

Puffins Would Disappear Without Three Key...

NRDCflix

875 views • 10 months ago

CC

Epic Animals Aren't Meant for Trafficking

NRDCflix

852 views • 10 months ago

CC

Protecting This Forest Can Help Stop Climate Change

NRDCflix

3.4K views • 1 year ago

CC

Why Aren't North Atlantic Right Whales Having Babies...

NRDCflix

695 views • 1 year ago

How to Sue the President

NRDCflix

1.5K views • 2 years ago

CC

NRDC Stories

▶ PLAY ALL

Flint's Court Battle for Clean Water

NRDCflix

310 views • 1 year ago

CC

Chicagoans Battle Manganese Dust Pollution

NRDCflix

2.9K views • 1 year ago

CC

Protecting Workers and Communities from Polluters

NRDCflix

260 views • 2 years ago

CC

Why Coal Has No Future

NRDCflix

10K views • 2 years ago

CC

Young People Can Stop Climate Change

NRDCflix

452 views • 2 years ago

CC

Voices

▶ PLAY ALL

Real-life stories from the people who inspire NRDC's work, in their own words.

The Spiritual Power of the

Citizens Speak Out Against

Trump's Attack on Our

Trump's Attack on Our

Trump's Attack on Our

Attachment 9

Search

Home | My Network | Jobs | Messaging | Notifications | Me | Work | Reactivate Premium for Free

Natural Resources Defense Council (NRDC)

Public Policy · New York, NY · 34,591 followers

The Earth's Best Defense

+ Follow | Learn more

3 people from your company were hired here

See all 855 employees on LinkedIn →

- Home
- About
- Life
- Jobs
- People
- Videos
- Ads

About

NRDC is the nation's most effective environmental action organization. We use law, science and the support of 1.3 million members and online activists to protect the planet's wildlife and wild places and to ensure a safe and... see more

See all

Company photos

+3 more photos

15 recently posted jobs

Learning and Developmen... New York, New York, Unite...

Learning and Developmen... New York, New York, Unite...

+13 more jobs

Community hashtags

Trending posts in #environment

1 reaction

Trending posts in #climatechange

There is no rationality that i... link.springer.com...

2 people are talking about this

Posts

All | Images | Documents | Videos | Sort by: Top

Natural Resources Defense Council (NRDC) + Follow

34,591 followers

2mo •

Happy Earth Day! Here's NRDC President & CEO Gina McCarthy reflecting on the first Earth Day in 1970, the progress that has been made since then and the challenges we face today. As Gina says, the climate challenges ahea ...see more

Similar pages

The Nature Conservancy
Non-profit Organization Management
1 school alumnus
+ Follow

Environmental Defense Fund
Environmental Services
1 school alumnus
+ Follow

Sierra Club
Political Organization
1 company alumnus
+ Follow

Show more

Attachment 10

Natural Resources Defense Council

Protecting our land, air, and water since 1970.

Follow

California: America's Climate Leader

The Golden State is stepping up its game to set the standard for powering our nation through 100 percent clean, renewable energy.

Rhea Suh
Sep 11

Attachment 11

Henry Henderson

Natural Resources Defense Council Midwest Program Director

Henry Henderson is the director of NRDC's Midwest office, which opened in Chicago in 2007. He was the founding commissioner for the City of Chicago's Department of Environment from 1992 to 1998, and served as the Illinois assistant attorney general from 1985 to 1987. As commissioner, he developed an environmental mission for the city, which included the development of the Chicago Brownfield Initiative, a natural resources rehabilitation initiative, the city's energy policies and utility regulations, and Chicago's clean air initiative to improve regional air quality while promoting economic development. He has taught environmental law and policy at the University of Chicago and the University of Illinois at Chicago. He blogs on NRDC's Switchboard.

A Year After Report, Flint Lacks Federal Aid and Safe Water

Congressional Hearings Should Reflect That Flint Is Not Fixed

Tests (or Lack Thereof) Show New Players Needed to Fix Flint

Flint Still Flubbed — More Answers, Accountability and Action Needed in Michigan

It's Prime Time For Ohio To Embrace Better Wind Energy Policies

EPA Flakes on Flint

Attachment 12

The Washington Post

Politics

Interior Department worked behind the scenes with energy industry to reverse royalties rule

By Juliet Eilperin October 6

Top Interior Department officials worked privately with energy industry representatives during the first weeks of the Trump administration to suspend a new accounting system that would have forced companies to pay millions of dollars more in royalties to the government, documents show.

The push to suspend the Obama-era rule, which is the subject of three federal lawsuits in Wyoming, took on a sense of urgency after an attorney for the coal company Cloud Peak Energy first suggested the move in late January. In email exchanges contained in more than 1,000 pages, obtained by the environmental group Natural Resources Defense Council under the Freedom of Information Act, top Interior officials raced to address industry concerns by halting a system that had just taken effect Jan. 1.

Under Secretary Ryan Zinke, the department has launched a broad reassessment of what to charge firms extracting oil, natural gas, coal and other minerals from federal lands and waters, with an eye toward boosting domestic energy production. Interior on Wednesday held the inaugural meeting of a new Royalty Policy Committee, with Zinke's energy counselor, Vincent DeVito, saying President Trump's desire for "energy dominance" will help guide royalty rules as well as other aspects of department decision-making.

"This committee has a job unlike any other in the past," DeVito said of the industry-heavy panel. It "has an agenda and authorization to pursue" energy development, he added.

Before Zinke or DeVito even arrived at Interior, though, career officials were reassessing how they should regulate these industries in light of Trump's victory. The discussion focused on whether to revisit a method the Office of

Natural Resources Revenue (ONRR) had adopted just months earlier for calculating royalties for minerals extracted on federal land.

The goal behind the change was to prevent firms from underpaying what they owe the government by selling coal to subsidiaries at an artificially low price — a strategy the government estimates costs taxpayers $75 million a year. Industry officials called the new requirements unclear and burdensome and wanted them halted before they had to file under the system for the first time.

On Jan. 31, according to the documents, a staffer emailed acting secretary Kevin "Jack" Haugrud with the message that Cloud Peak Energy lawyer Kelly Johnson and other industry attorneys wanted to meet with him and a member of Trump's transition team at Interior. Haugrud subsequently checked with the solicitor for the Rocky Mountain Region, Matt McKeown.

"If this is about [the royalty] valuation rule, then I think a meeting is timely," McKeown replied the next day. "An internal discussion in advance would likely be a good idea."

By Feb. 6, other Interior officials had been enlisted to work to stay the rule so the new accounting system did not take effect. "Timeline?" one ONRR staffer emailed another. "ASAP," her colleague replied.

Three days later, as Interior officials emailed how they would justify the change, another replied, "RIP rule."

By Feb. 15, Interior attorney Matthew Wheeler wrote a group at ONRR to say he was conferring with lawyers for the industry groups challenging the 2016 rule to see if they could submit a letter formally requesting a stay.

"Like us, they have a number of hoops to jump through to get each client to sign off on the final product," Wheeler noted.

Less than two weeks later — after Haugrud had personally edited the notice Interior prepared for the Federal Register — the notice posted. Interior later rescinded the rule altogether, a move that took effect Sept. 6.

"What's deeply troubling here is how quickly Interior sprang into action at industry's command and the lengths they went to do industry's bidding," said Theo Spencer, a senior policy advocate in NRDC's land and wildlife program. "Getting a notice prepared from scratch and published in the Federal Register in less than a month is close to unheard of."

Interior officials declined to comment on the released emails, citing the ongoing litigation and the department's subsequent decision to revoke the rule.

Zinke said in August that he acted because the higher costs that companies would incur "had the potential to decrease exploration and production on federal lands, both onshore and offshore, making us rely more and more on imports of oil and gas."

Rescinding the regulation, Zinke added, "restores our economic freedom by ensuring our energy independence."

California and New Mexico, each of which receives a share of the minerals royalties collected by the federal government, challenged the decision to stay the rule in the U.S. District Court for the Northern District of California. U.S. Magistrate Judge Elizabeth Laporte decided in their favor last month, finding that the administration had violated the Administrative Procedure Act by not taking public comment first. But Laporte declined to reinstate the rule because Interior had already announced its plan to pull it. The two states are deciding whether to challenge that revocation in court.

Cloud Peak Energy spokesman Rick Curtsinger said in an email on Wednesday that the lawsuits before the U.S. District Court in Wyoming are pending "while the parties discuss the impact of the repeal on the claims."

Curtsinger, whose company is represented on the department's royalty committee, said the existing system has "provided tremendous benefits to the American people."

"Nearly 40 percent of the selling price of every ton of federal coal mined in the [Powder River Basin in Wyoming and Montana] consists of taxes, fees and royalties, making it among the highest taxed commodities in the world," he wrote. "The Obama administration's rewrite was part of its activist . . . campaign to keep the nation's valuable fossil fuel resources in the ground."

16 Comments

Juliet Eilperin is The Washington Post's senior national affairs correspondent, covering how the new administration is transforming a range of U.S. policies and the federal government itself. She is the author of two books—one on sharks, and another on Congress, not to be confused with each other—and has worked for the Post since 1998. Follow @eilperin

Attachment 13

Newsroom

NEWSROOM PROGRAM NEWS

MAY 2, 2016 Go Back

Discovery Channel's Sonic Sea Journeys Deep Into the Ocean Uncovering the Devastating Impact Man-Made Noise Has on Marine Life and What Can Be Done to Stop the Damage to These Creatures Who Are a Crucial Part of the Circle of Life

– Discovery Impact Special Premieres May 19th –

– Narrated by Oscar®-Nominated Actress Rachel McAdams And Featuring An Interview with Grammy® Award-Winning Artist Sting –

– Produced by the Natural Resources Defense Council and Imaginary Forces in association with the International Fund for Animal Welfare –

Everywhere on Earth we can hear the songs of life. From small insects to the largest animals on the planet, our world is made up of the sounds of these creatures living and communicating with one another. This is even more apparent deep down in the darkness of the sea, where whales and other marine life depend on sound to mate, find food, migrate, raise their young and defend against predators. Yet, their symphony of life is being disrupted by the industrialized noise that has become commonplace in our oceans today—with tragic and deadly costs.

Created in partnership with Natural Resources Defense Council (NRDC), Imaginary Forces and International Fund for Animal Welfare (IFAW), SONIC SEA travels beneath the ocean's surface to uncover the damaging consequences of increased ocean noise pollution and what can be done to stop it. Narrated by Academy® Award-nominated actress Rachel McAdams and featuring interviews with marine ecologists, ocean life experts, and wildlife activists, including Grammy Award-winning musician, human rights and environmental activist Sting, SONIC SEA highlights how noise from a range of man-made sources has affected whales in recent years, including the mass stranding of whales around the planet. The film uncovers how better ship design, speed limits for large ships, quieter methods for underwater resource exploration, and exclusion zones for sonar training can work to reduce the noise in our oceans and stop the deaths of our ocean's beloved creatures, as long as society has "the political will to solve it."

Premiering as part of DISCOVERY IMPACT, a series of groundbreaking documentaries focusing on humankind's impact on the environment and what individuals and society as a whole can do to solve some of the largest problems facing the planet, SONIC SEA premieres Thursday, May 19 at 9 p.m. ET/PT, exclusively on Discovery Channel. Upcoming Discovery Impact Documentaries include TOUCAN NATION (July 30) and KILLING THE COLORADO (August 6).

Over the last century, extremely loud noise from commercial ships, oil and gas exploration, naval sonar exercises and other sources has transformed the ocean's delicate acoustic habitat, challenging the ability of whales and other marine life to prosper and ultimately to survive.

"March 15, 2000: The day of infamy as far as I'm concerned," explains Kenneth C. Balcomb, a whale researcher and a former U.S Navy officer who was living in Bahamas.

On this day, Balcomb and his team discovered whales swimming dangerously close to the shore. "They're supposed to be in deep water. So I pushed it back out to sea," explained Balcomb.

As the day progressed more and more were discovered off the coast and ultimately various groups of whales were found on the shore. SONIC SEA shines a light on the findings of those incidents which led to a new understanding of the detrimental impact of ocean noise on marine life

“There’s different ways that sounds can affect animals,” explains IFAW Animal Rescue Program Director Katie Moore. “There’s that underlying ambient noise level that’s rising, and rising, and rising that interferes with communication and their movement patterns. And then there’s the more acute kind of traumatic impact of sound, that’s causing physical damage or a really strong behavioral response. It’s fight or flight.”

Because of the events in the Bahamas and others around the globe, researchers worked to study the direct affect the noise has on wildlife living in the ocean and have come to staggering conclusions. One study conducted off of the coast of Boston revealed that North Right Whales lost up to 80 percent of their ability to hear the songs of their friends and mates. While their cousins, the Southern Right Whales, who live in the Southern Hemisphere where there is a fraction of the shipping compared to the north, are thriving and multiplying.

This noise is “ripping the communication system apart,” making it almost impossible to mate, find food and ultimately survive. And now, the species as a whole is in a dire situation.

“There may be 450 of them left in the entire ocean,” explains Christopher W. Clark, Ph.D, Senior Scientist at the Bioacoustics Research Program, Cornell Lab of Ornithology. “That species is fighting for its life right now.”

SONIC SEA also explores how the use of sonar by the U.S Navy and other navies around the world is contributing to whale strandings. While sonar helps to protect our ships and those naval officers aboard the ships by detecting activity from enemy forces in the water, it also can have a debilitating effect on an ocean’s whale population. The deafening sound it releases forces many whales to go silent, stop communicating with their fellow whales, and often abandon the ocean they were calling home. Although the two sides might seem at opposing ends of the spectrum, many working in the industry don’t believe that they are mutually exclusive.

In SONIC SEA, Honorable Steven Honigman, ret. U.S Navy, comments that, “I don’t believe that national security and environmental protection are inconsistent at all. I think there has to be an accommodation between those two principles, where the Navy can operate in a way that has the minimal impact upon the environment and still perform its training, and if necessary, its mission.”

New solutions, including quieter shipping and seismic testing technologies, exist to balance industry needs with the protection of marine mammals.

“It won’t cure the problem, there will still be impacts, but it would at least reduce the fever,” said Michael Jasny, director of NRDC’s Marine Mammal Protection Project. “The one good thing about ocean noise is that when you stop making noise, it goes away.”

SONIC SEA won the Jury Award and the John de Graff Environmental Filmmaking award when it premiered at the Wild & Scenic Film Festival in January.

SONIC SEA is produced by the Natural Resources Defense Council and Imaginary Forces in association with the International Fund for Animal Welfare and Diamond Docs. Directed and produced by Michelle Dougherty and Daniel Hinerfeld; written by Mark Monroe' editor, Christopher Johnson; scored by, Heitor Pereira; director of photography, Stacy Toyama; executive producers, Chip Houghton, Peter Frankfurt and Joel Reynolds; co-producers Lisa Whiteman and Franceska Bucci, associate producers; Shawna Moos, Patrick R. Ramage, Dunja Vitolic, Kashina Kessler; consulting producers, Michael Jasny, Tristan Bayer, and Bronwyn Barkan. For Discovery Channel: supervising producer, Jon Bardin; executive producer, John Hoffman.

Google Oceans and SpaceQuest, Ltd provided data on global ship traffic used in several of the film's animations.

About Discovery Channel

Discovery Channel is dedicated to creating the highest quality non-fiction content that informs and entertains its consumers about the world in all its wonder, diversity and amazement. The network, which is distributed to 100.8 million U.S. homes, can be seen in 210 countries and territories, offering a signature mix of compelling, high-end production values and vivid cinematography across genres including, science and technology, exploration, adventure, history and in-depth, behind-the-scenes glimpses at the people, places and organizations that shape and share our world. For more information, please visit www.discovery.com.

About Discovery Communications

Discovery Communications (Nasdaq: DISCA, DISCB, DISCK) is the leader in global entertainment reaching 3 billion cumulative viewers in more than 220 countries and territories. Discovery satisfies curiosity, entertains and inspires viewers with high-quality content through global brands, led by Discovery Channel, TLC, Investigation Discovery, Animal Planet, Science and Turbo/Velocity, as well as U.S. joint venture network OWN: Oprah Winfrey Network, and through the Discovery Digital Networks portfolio, including Seeker and SourceFed. Discovery owns Eurosport, the leading pan-regional sports entertainment destination across Europe and Asia-Pacific. Discovery also is a leading provider of educational products and services to schools, including an award-winning series of K-12 digital textbooks, through Discovery Education. For more information, please visit www.discoverycommunications.com.

About the Natural Resources Defense Council

The Natural Resources Defense Council (NRDC) is an international nonprofit environmental organization with more than 2 million members and online activists. Since 1970, our lawyers, scientists, and other environmental specialists have worked to protect the world's natural resources, public health, and the environment. NRDC has offices in New York City, Washington, D.C., Los Angeles, San Francisco, Chicago, Bozeman, MT, and Beijing. Visit us at www.nrdc.org and follow us on Twitter @NRDC.

About IFAW

Founded in 1969, IFAW rescues and protects animals around the world. With projects in more than 40 countries, we rescue individual animals, work to prevent cruelty to animals, and advocate for the protection of wildlife and habitats. For more information, visit www.ifaw.org. Follow us on Facebook/IFAW and Twitter @action4ifaw

Attachment 14

Marine Policy 47 (2014) 71–75

Contents lists available at ScienceDirect

Marine Policy

journal homepage: www.elsevier.com/locate/marpol

Short Communication

The requirement to rebuild US fish stocks: Is it working?

Kimberly Lai Oremus [a,*], Lisa Suatoni [b], Brad Sewell [b]

[a] Columbia University, Sustainable Development PhD Program, School of International and Public Affairs, Earth Institute, 420 West 118th Street, 6th Floor, Mailbox #3, New York, NY 10027, United States
[b] Natural Resources Defense Council, 40 W 20th Street, New York, NY 10011, United States

ARTICLE INFO

Article history:
Received 9 September 2013
Received in revised form
30 January 2014
Accepted 10 February 2014
Available online 28 February 2014

Keywords:
Magnuson–Stevens Act
Sustainable Fisheries Act
Rebuilding provisions
US fisheries

ABSTRACT

The Magnuson–Stevens Fishery Conservation and Management Act (MSA) was amended in 1996 to require that overfished stocks be rebuilt in as short a time period as possible, not to exceed 10 years, with limited exceptions. This comment examines the basic but important question of whether the implementation of rebuilding plans under the 1996 amendments has in fact been associated with biomass recovery. Specifically, for each of the 44 stocks examined, this analysis compares the biomass trend before rebuilding plan implementation to the trend after rebuilding plan implementation using a linear trend-break model. The analysis demonstrates a statistically significant positive association between the implementation of rebuilding plans and standardized biomass in 19 of 44 stocks. None of the 44 stocks examined showed a statistically significant negative association. The analysis showed a strong temporal relationship between the implementation of the policy and rebounds in fish stocks.

1. Introduction

The 1996 passage of the Sustainable Fisheries Act (SFA), which reauthorized and amended the Magnuson–Stevens Fishery Management and Conservation Act (MSA), marked a sea change in the United States' approach to fishery management [1]. In response to a large number of depleted fish stocks in federal waters, particularly in the New England region, a requirement was added to the law that rebuilding plans be developed for overfished stocks [2]. These plans must include time periods for rebuilding that are "as short as possible, … not [to] exceed 10 years except in cases where the biology of the stock of fish, other environmental conditions, or management measures under an international agreement in which the United States participates dictate otherwise [3]".

Since its enactment, the new requirement to expeditiously rebuild depleted fish populations has been a focal point of debate, eliciting both support [4,5] and criticism [6]. However, despite the political attention, there has been little statistical examination of whether the provision is working.

Several prior studies do provide an accounting of progress. The first study, published 7 years after the implementation of the rebuilding requirement, found "disappointing" early results, with only three of 76 overfished stocks successfully rebuilt [7]. A more recent report[1] found mounting successes, with 48% of stocks rebuilt in 2013 [8].

The MSA is up for reauthorization in 2014, and the rebuilding requirements may be among the provisions considered for amendment. Thus, the time is right to evaluate the rebuilding requirement's efficacy. This study is the first to explore whether the implementation of the rebuilding policy is correlated with statistically significant changes in population trends of overfished fish stocks.

2. Materials and methods

This study identified 62 fish stocks designated as overfished by the National Marine Fisheries Service (NMFS) and subjected to rebuilding plans following the SFA's enactment.[2] Of these 62 stocks, 44 were identified for which stock assessment data are sufficient to assess biomass trends since the plan's implementation. To satisfy this criterion, a stock must have been in a rebuilding plan since before 2010 and had at least one stock assessment since the plan's implementation.

[1] This assessment identified 28 of 44 fish stocks as "rebuilding successes", based upon the stocks achieving either their rebuilding targets or at least 50% of their rebuilding targets and at least a 25% increase in abundance since rebuilding plan start.

[2] This excludes 13 internationally managed stocks, which are subject to different rebuilding requirements.

* Corresponding author.
E-mail addresses: kl2537@columbia.edu (K.L. Oremus), lsuatoni@nrdc.org (L. Suatoni), bsewell@nrdc.org (B. Sewell).

http://dx.doi.org/10.1016/j.marpol.2014.02.007
0308-597X

Biomass and fishing mortality data were compiled from the most recent stock assessments conducted by NMFS. Biomass proxies such as spawning stock biomass were used when they were relied on by the most recent stock assessment. These assessments are utilized by NMFS to evaluate the progress of rebuilding plans and are the best available information. Still, it should be noted that the assessments are limited by how recently they were conducted, the quality of the data sources, and uncertainty in the models used. The present study necessarily excluded more than 200 federally managed fish stocks for which assessments do not exist or are considered out of date by NMFS, and therefore stock status is considered unknown.

For each stock, standardized biomass (biomass or proxy normalized by estimate of biomass at maximum sustainable yield) was analyzed from 1976 (or earliest date available after 1976) to the date the stock was declared rebuilt (or, if the stock has not been rebuilt, the most recent date available). The start date, 1976, was chosen because this is when the MSA was enacted. The MSA significantly changed the fisheries management landscape in the United States, including the creation of a 200-mile conservation zone and the regional fishery management council system.

Since there is no data on overfished stocks that did not receive the policy treatment (and are not listed under the Endangered Species Act), a proper control group does not exist. Following event study literature for testing whether pre-trend growth rates are different from post-trend growth rates [9,10], a continuous linear trend-break model[3] with fishery-level intercepts and slopes was fit to the standardized biomass data using ordinary least squares (Fig. 1). The model assumes similar measurement errors within regions, because of similarities in how fish stocks are assessed and managed within a region by each of the regional fishery management councils. The trend break year was defined using the year of rebuilding plan implementation [8] and its significance was evaluated using *t*-tests. A Bonferroni correction was applied to account for errors from running multiple tests.

3. Results and discussion

This analysis compared the standardized biomass trend for each stock before rebuilding plan implementation to the trend after implementation. In this linear model, 19 of 44 stocks showed statistically significant positive slope changes (trend breaks) in biomass after rebuilding provisions were implemented (Fig. 2). Statistical significance was defined at the 5% level with a Bonferroni correction. None of the 44 stocks showed a statistically significant negative trend break. This allows for the rejection of the null hypothesis that there was no change in biomass trends following rebuilding plan implementation. In other words, there is a strong relationship between the implementation of the rebuilding requirement and rebounds in fish stocks. These results are consistent with observations that stock depletion is reversible when fishing mortality is effectively controlled [11–13].

As a placebo test, the same model was applied to biomass data only from the years prior to rebuilding plan implementation, and then to biomass data only from the years after rebuilding plan implementation. In both cases the trend-break model was run multiple times using randomly chosen trend-break dates. In four of the five tests, none of the 44 stocks examined showed significant trend breaks. In the fifth test, which was performed on post-implementation data using an event date of plus-3 years, six showed significant positive trend-breaks and three negative. Taken as a whole, these checks reinforce the conclusion that the positive relationship between rebuilding plans and biomass recovery is not random.

The regressions in this analysis were run by region rather than by individual fishery because fisheries are managed at the regional level, and because estimating the errors by region compensates for limitations in the data. Not only are the fishery-level time series relatively limited for some stocks, but stock modelers use different modeling techniques and measures of uncertainty are unavailable. However, running the regressions independently by fishery reduces standard errors and would only yield more positive trend breaks,[4] strengthening this study's main findings.

There may be concern as to whether this study's linear model favors stocks with lower biomass variance. Lower variances could result from a natural cause, such as slow-growing stocks or stocks with demersal habitat [14], but they could also be the result of stock assessment scientists smoothing the biomass data with interpolation. However, weighting the trend-break model to favor high-variance stocks using a weighted least-squares regression produced only marginally fewer, positive results.[5] Thus the main study's core finding is not simply the result of artificially low-variance stock assessment-data, and controlling for inter-annual variability would likely yield unchanged or only marginally stronger conclusions.

The results in this study are also consistent with the significant progress in fish stock rebuilding seen in NMFS' reports on the status of stocks [15], while providing an additional lens through which to view and quantify that progress. NMFS generally considers a stock to be rebuilt as soon as its estimated biomass reaches the level that produces maximum sustainable yield (B_{MSY}). This study examined whether there had been a sustained change over time in a stock's biomass trend following rebuilding plan implementation sufficient to produce a statistically significant trend break. There is substantial overlap between the 19 stocks for which this study found significant positive trend breaks and the 21 that have achieved B_{MSY},[6] NMFS' threshold for declaring a stock rebuilt. Of the 19 stocks with significant trend breaks, NMFS has identified 14 as achieving rebuilding targets.

NMFS considers the number of stocks rebuilt so far to be encouraging [15], especially given that rebuilding plans are generally designed to achieve B_{MSY} by a designated target date with 50% probability of success, and many stocks have not yet reached their target dates. Only 17 of the 44 stocks in this study have reached their target dates.

While further study is required to establish causality, this study makes it clear that the fish population rebounds are non-random and linearly correlate with the implementation of rebuilding plans under the Magnuson–Stevens Act. Future research should examine the factors that lead to rebuilding successes, as well as those involved in unsuccessful responses to rebuilding plans. Previous reviews of efforts to rebuild fish stocks worldwide identify numerous primary causes for failures, including insufficient or delayed decreases in fishing mortality, systematic underreporting

[3] $y_{it}=\beta_{0i}+\beta_{1i}t_i+\beta_{2i}(t-t_{0i})I_{(t\geq t0i)}+\varepsilon_{it}$ where y_{it} is the std. biomass for stock $i=1,\ldots,44$ at time $t=1976,\ldots$, time of rebuild or time of most recent stock assessment; t_{0i} is the rebuild implementation date for stock i; ε_{it} is i.i.d. $N(0,\sigma^2_{r(i)})$; and $r(i)$ is the region of stock i.

[4] Running the regressions independently by fishery yielded 29 significant positive trend-breaks and zero negative.

[5] By weighting this study's model using standardized biomass variance by stock, stocks with higher variances are favored, but still found the same stocks had significant trend breaks with the exception of black sea bass, cowcod, monkfish south and haddock Gulf of Maine. Some of these stocks have naturally low biomass variance due to their long generation times and benthic habitat.

[6] Nineteen of these stocks, excluding Gulf of Maine haddock and summer flounder that currently do not have biomass at B_{MSY}, have been formally designated as "rebuilt" by NMFS. However, two additional stocks—Mid-Atlantic tilefish and Southern Georges Bank/Mid-Atlantic red hake—are recognized by NMFS as exceeding their rebuilding targets even though they are not currently designated as rebuilt.

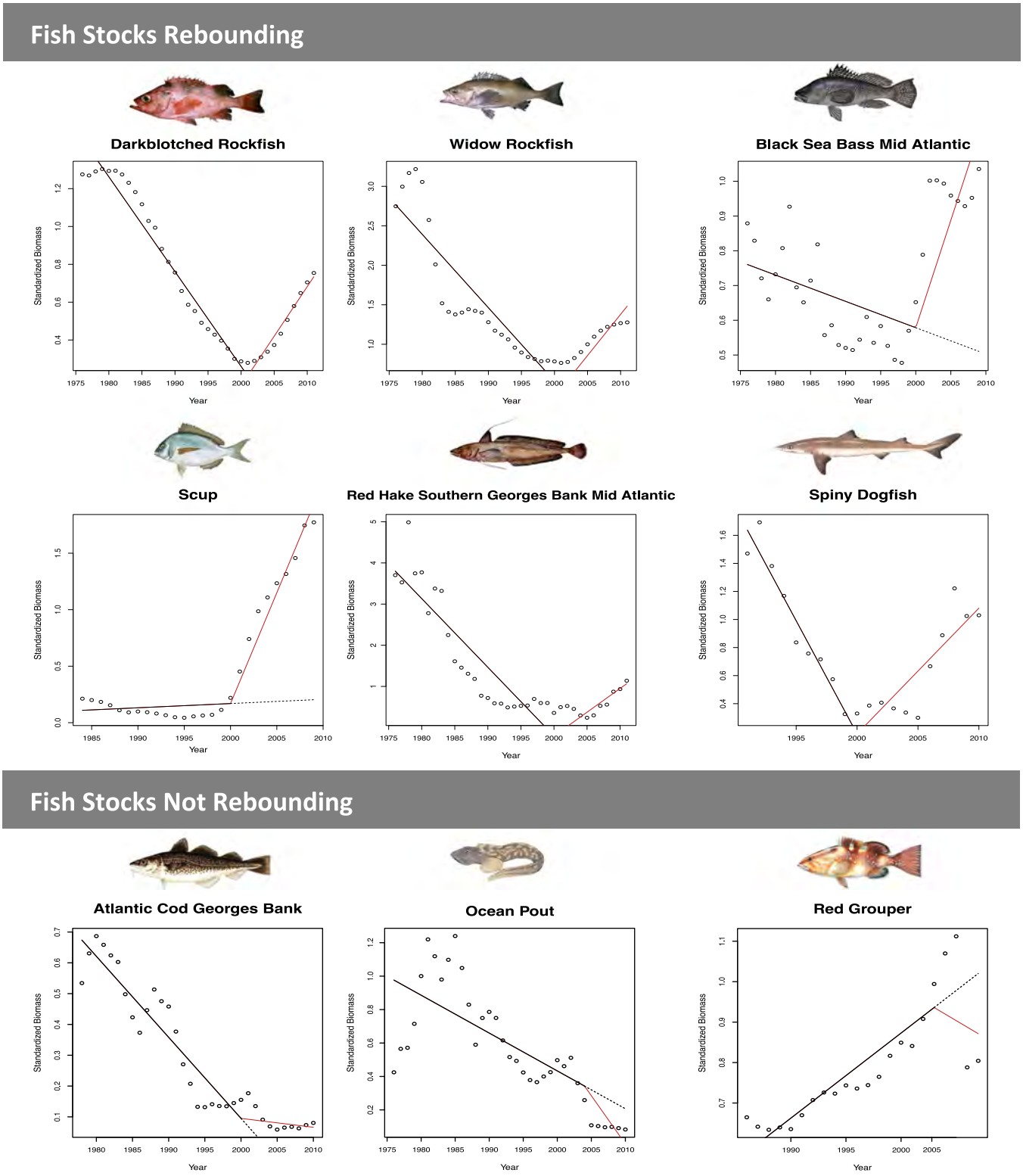


Fig. 1. Each graph plots standardized biomass (open circles) based on NMFS stock assessments. The solid black line represents a linear model of the trend prior to the rebuilding plan. The dotted line represents the hypothetical continuation of that trend. The red line (grey line in print version) is the model. The first two rows show statistically significant, positive trend breaks with policy implementation. The last row shows no statistically significant changes in trend with policy implementation.

of catches, and scientific uncertainty [13]. Less frequently, depensatory mortality and unfavorable climate patterns appear to be important factors in sluggish recovery [13].

This study also underscores the need for improved stock-assessment data in order to better understand the rebuilding requirement's impacts. Monitoring of all 446 federally managed stocks would facilitate comparisons between those in rebuilding plans and those that are not. More frequent and robust stock assessments, timelier reporting of data, and increased understanding of the biology and ecology of each stock would enable

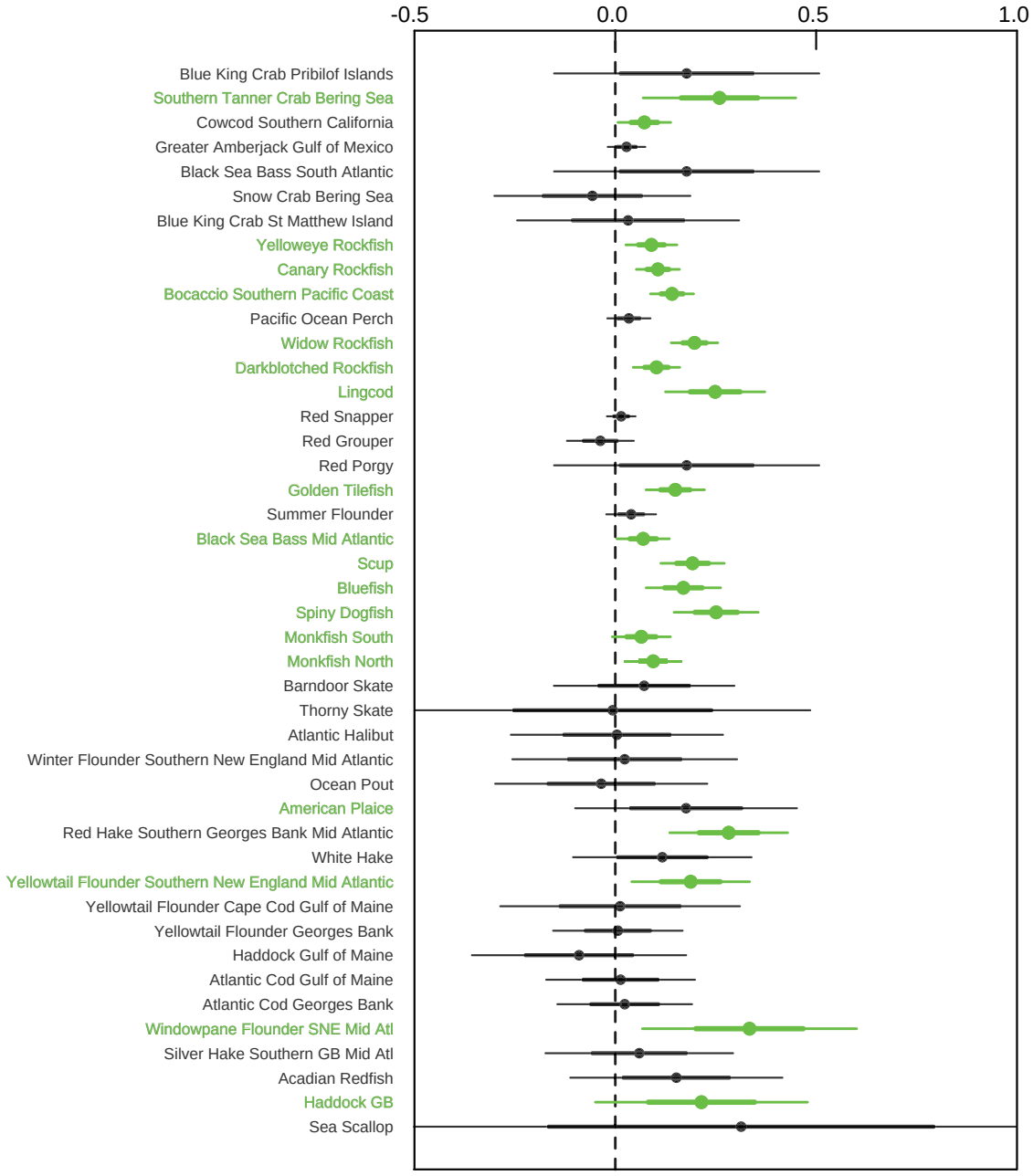


Fig. 2. Trend break coefficient estimates by stock. For each stock, the black dot is the trend-break coefficient, which measures the difference in the slope of the trend and after rebuilding. A coefficient above zero indicates a positive change in the biomass trend, while a coefficient below zero would represent a negative change. The bold and non-bold portions of the line represent one and two standard deviations, respectively.

more nuanced analysis of the relevant population trends. Finally, greater transparency in the stock assessment methodology, including confidence intervals, would aid in developing realistic error terms.

4. Conclusion

This is the first study to rigorously examine an important indicator of the efficacy of the MSA's rebuilding requirements: biomass rebound. Further research will assist in the understanding of the specific causes of biomass recovery, or lack thereof, for each stock. Nevertheless, this study found a strong association between implementation of the rebuilding requirements added to federal law in 1996 and recovery of depleted fish stocks.

Acknowledgments

We would like to Seth Atkinson, Dave Newman, Melissa Hedges-Monk, and Marina Zaiats for helping to collect data for this project. We are particularly indebted to Seth Atkinson for helping to identify the fisheries stocks to be used in the analysis. This research was funded in part by grants from The David and Lucille Packard Foundation, the Kathryn W. Davis Peace by Pieces Fund, the Panaphil Foundation, The Prospect Hill Foundation, and the Sandler Foundation.

References

[1] Baur DC, Eichenberg T, Sutton M, editors. American Bar Association; 2007.

[2] An annotated guide to the major provisions of the Sustainable Fisheries Act. Ocean Coast Law J 1997;3:307–26.
[3] Sustainable Fisheries Act: amendments to the Magnuson Fishery Conservation and Management Act, Magnuson–Stevens Act. 1996; 16 U.S.C. §1801 et seq.
[4] Safina C, Rosenberg AA, Myers RA, Quinn TJ, Collie JS. US ocean fish recovery: staying the course. Science 2005;309(5735):307–26.
[5] Pauly D. How healthy are our fisheries? New York Times; 2011.
[6] Hilborn R. Let us eat fish. New York Times; 2011.
[7] Rosenberg AA, Swasey JH, Bowman M. Rebuilding US fisheries: progress and problems. Front Ecol Environ 2006;4(6):303–8.
[8] Sewell B, Atkinson S, Newman D, Suatoni L. Bringing back the fish: an evaluation of US fisheries rebuilding under the Magnuson–Stevens Fishery Conservation and Management Act (unpublished report). New York: Natural Resources Defense Council; 2013.
[9] Wooldridge JM. Econometric analysis of cross section and panel data. Cambridge: MIT Press; 2002.
[10] Christopher C, Gaines SD, Lynham J. Can catch shares prevent fisheries collapse? Science 2008;321(5896):1678–81.
[11] Powers JE. Principles and realities for successful stock recovery—a review of some successes and failures. ICES Theme Session. 2003: U:12; p. 1–14.
[12] Mace PM. In defense of fisheries scientists, single-species models and other scapegoats: confronting the real problems. Mar Ecol Prog Ser 2004;274:285–91.
[13] Murawski SA. Rebuilding depleted fish stocks: the good, the bad, and, mostly, the ugly. ICES J Mar Sci 2010;67(9):1830–40.
[14] Spencer PD, Collie JS. Patterns of population variability in marine fish stocks. Fish Oceanogr 1997;6(3):188–204.
[15] NOAA. Status of stocks 2012: annual report to Congress on the status of US fisheries. National Oceanic and Atmospheric Administration, National Marine Fisheries Service; 2012.

Attachment 15

ISSUE BRIEF

JUNE 2014
IB:14-05-C

The Untapped Potential of California's Water Supply: Efficiency, Reuse, and Stormwater

California is suffering from a third year of drought, with near-record-low reservoirs, mountain snowpack, soil moisture, and river runoff. As a direct result, far less water than usual is available for cities, farms, and natural ecosystems. There are far-reaching effects that will intensify if dry conditions persist. Several response strategies are available that will provide both near-term relief and long-term benefits. This report examines the significant potential contributions available from four priority opportunities: improved efficiency in urban and agricultural water use, reuse and recycling of water, and increased capture of local rain water.

PACIFIC INSTITUTE

NRDC
THE EARTH'S BEST DEFENSE

California is a land of hydrological extremes, from water-rich mountains and redwood forests in the north to some of the driest deserts in North America in the south. It suffers both epic floods and persistent droughts. The existing water infrastructure and management systems reflect these extremes, with massive dams, canals, and pumping stations to store and transfer water, and hundreds of intertwined laws, institutions, and organizations promoting overlapping and sometimes conflicting water interests. The drought could end next year or it could continue, with even greater consequences in the coming years. But even during good years, disputes over water are common and claims of water shortages rampant. Dry years magnify disagreements over allocation, management, and use of California's water resources.

For much of the 20th century, California's water supply strategy has meant building reservoirs and conveyance systems to store and divert surface waters, and drilling groundwater wells to tap our aquifers. Hundreds of billions of federal, state, and local dollars have been invested in these supply options, allowing the state to grow to nearly 40 million people with a $2 trillion economy (LAO, 2013; Hanak et al., 2012). But traditional supply options are tapped out. Rivers are over-allocated even in wet years. There is a dearth of new options for surface reservoirs, and those that exist are expensive, politically controversial, and offer only modest improvements in water supply for a relatively few users. Groundwater is so severely overdrafted that there are growing tensions among neighbors and damage to public roads, structures, and, ironically, water delivery canals from the land subsiding over depleted aquifers.

The good news is that solutions to our water problem exist. They are being implemented to varying degrees around the state with good results, but a lot more can be done. During a drought as severe as the current one, the incentives to work cooperatively and aggressively to implement solutions are even greater. In this report, we examine the opportunities for four cost-effective and technically feasible strategies—urban and agricultural water conservation and efficiency, water reuse, and stormwater capture—to improve the ability of cities, farmers, homeowners, and businesses to cope with drought and address longstanding water challenges in California. We conclude that these strategies can provide 10.8 million to 13.7 million acre-feet per year of water in new supplies and demand reductions, improving the reliability of our current system and reducing the risks of shortages and water conflicts.

NATURE OF THE CHALLENGE: THE "GAP"

California's water system is out of balance. The current water use pattern is unsustainable, and there is a large and growing gap between the water desired and the water made available by nature. Human demands for water in the form of water rights claims, agricultural irrigation, and growing cities and suburbs greatly exceed—even in wet years—volumes that can be sustainably extracted from natural river flows and groundwater aquifers. Major rivers, such as the San Joaquin, have been entirely de-watered. Declines in groundwater levels in some areas due to overpumping of groundwater are measured in hundreds of vertical feet and millions of acre-feet.

Estimates of the overall "gap" are difficult because large volumes of water use are not measured or reported, California's natural water supply varies greatly between wet and dry years, and because water "demand" can be artificially inflated by over-allocation of rivers, inefficient use, price subsidies, the failure to prevent groundwater overdraft, and other hard limits on supply. But there are a wide variety of signs of the gap:

Sacramento-San Joaquin River Delta

The Sacramento-San Joaquin River Delta illustrates the unsustainable gap between how much water we take from our rivers and how much those rivers can provide. The Delta is vitally important to California. It is the primary hub for moving water from north to south. It is home to hundreds of species of birds, fish, and wildlife (DSC, 2013), including two-thirds of the state's salmon and at least half of the Pacific Flyway migratory water birds (USFWS, 2001). It is also a vibrant farming community. But excessive water diversions have contributed to a crisis that threatens the Delta's ability to perform any of these functions. In response to this crisis, in 2009, the State Legislature directed the State Water Resources Control Board (State Board) to determine how much water the Delta would need to fully protect public trust resources in the Delta.[1] For an average weather year, the State Board found that substantially increased flows from the Sacramento and San Joaquin River basins through the Delta into San Francisco Bay are needed to restore and maintain viable populations of fish and wildlife under existing conditions.[2] The Board's findings indicate that we currently divert almost 5 million acre-feet more water in an average year from the Delta than is compatible with a healthy Delta.[3] While these findings were designed to inform future planning decisions without considering other changes to the system or balancing other beneficial uses, the State Board's determination illustrates the yawning gap between our water demands in California and how much our surface waters can supply.

Groundwater Overdraft

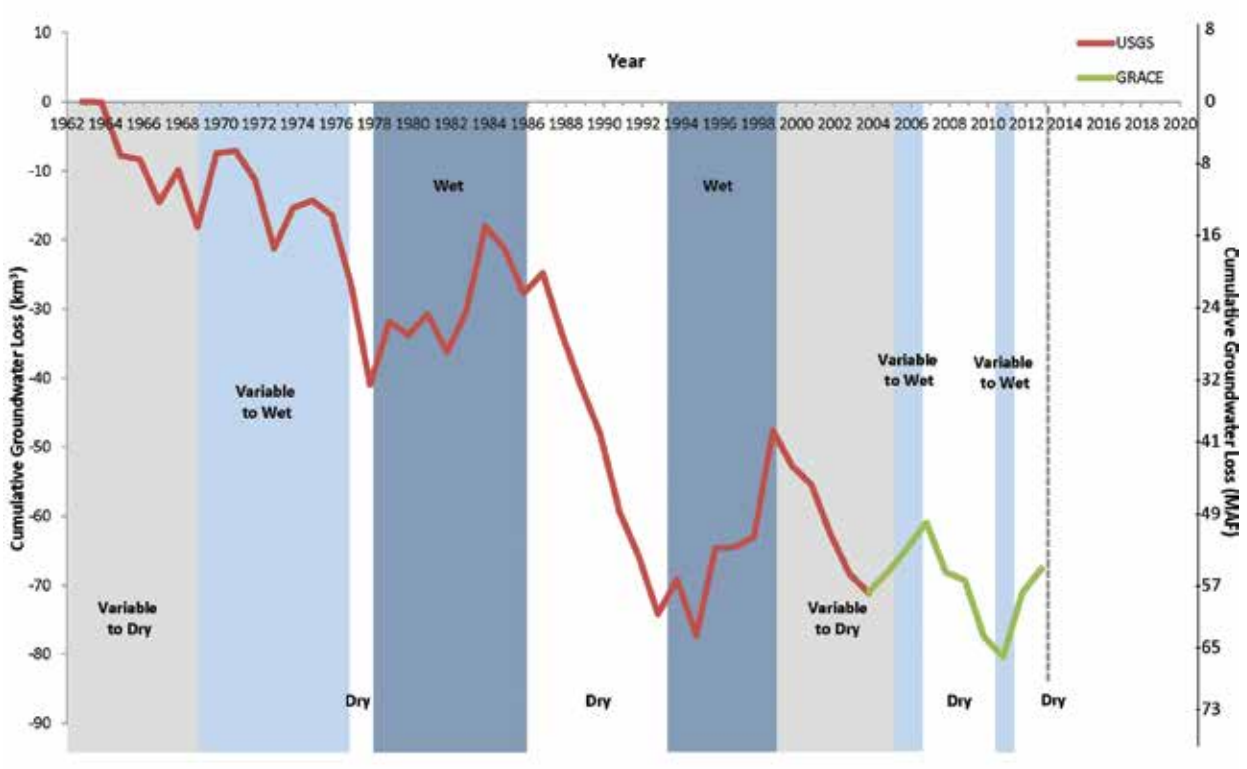
Groundwater is a vital resource for California. In average years, it provides nearly 40 percent of the state's water supply. That number goes up to 45 percent in dry years and close to 60 percent in a drought (DWR, 2014a). Moreover, many small- and medium-sized communities, such as Lodi, are completely dependent on groundwater. A clear indicator of the gap between water supply and water use in California is the extensive and unsustainable overdraft of groundwater, i.e., groundwater extracted beyond the natural recharge rate of the aquifer. Chronic overdraft has led to falling groundwater levels, dry wells, land subsidence, decreased groundwater storage capacity, decreased water quality, and stream depletion (Borchers et al., 2014).

As shown in Figure 1, groundwater levels are declining across major parts of the state. According to the Department of Water Resources (2014a), since spring 2008, groundwater levels have dropped to all-time lows in most areas of the state and especially in the northern portion of the San Francisco Bay hydrologic region, the southern San Joaquin Valley, and the South Lahontan and South Coast hydrologic regions. In many areas of the San Joaquin Valley, recent groundwater levels are more than 100 feet below previous historic lows. While some groundwater recharge occurs in wet years, that recharge is more than offset by pumping in dry and even average years, with over 50 million acre-feet of groundwater having been lost over the last half century (UCCHM, 2014). A comprehensive statewide assessment of groundwater overdraft has not been conducted since 1980, and there are major gaps in groundwater monitoring.[4] DWR has been estimating with considerable uncertainty that overdraft is between 1 million and 2 million acre-feet per year (DWR, 2003).

There are strong indications, however, that groundwater overdraft is worsening. Recent data indicates that the Sacramento and San Joaquin River Basins collectively lost over 16 million acre-feet of groundwater between October 2003 and March 2010, or about 2.5 million acre-feet per year (Famiglietti, 2014). This period captured a moderate drought, and thus we would expect overdraft to be higher than in non-drought periods. But while groundwater levels increased in 2011 and 2012, they did not fully recover to pre-drought levels, resulting in a net loss in groundwater storage at time when California enters a far more severe drought.

The gap between water supply and use from the state's groundwater basins and from the Sacramento-San Joaquin Delta alone exceeds 6 million acre-feet of water per year. We know that this underestimates the gap, as numerous studies have identified considerable unmet environmental flow objectives in other parts of the state (Hayden and Rosekrans, 2004). Moreover, we know that these "gaps" are expected to grow with the increasing challenges posed by population growth and climate change (DWR, 2013a).

Figure 1. Cumulative groundwater loss (in km³ and million acre-feet) for California's Central Valley since 1962



Note: Cumulative groundwater losses (cubic km and million acre-ft) in California's Central Valley since 1962 from USGS and NASA GRACE data. Figure from UCCHM (2014) and extends figure B9 from *Faunt* [2009]. The red line shows data from USGS calibrated groundwater model simulations [Faunt, 2009] from 1962-2003. The green line shows GRACE-based estimates of groundwater storage losses from *Famiglietti* et al. [2011] and updated for UCCHM(2014). Background colors represent periods of drought (white), of variable to dry conditions (grey), of variable to wet conditions (light blue) and wet conditions (blue). Groundwater depletion mostly occurs during drought; and progressive droughts are lowering groundwater storage to unsustainable levels.

Source: UC Center for Hydrologic Modeling (UCCHM), 2014. Water Storage Changes in California's Sacramento and San Joaquin River Basins From GRACE: Preliminary Updated Results for 2003-2013. University of California, Irvine UCCHM Water Advisory #1, February 3, 2014. Available at https://webfiles.uci.edu/jfamigli/Advisory/UCCHM_Water_Advisory_1.pdf.

Figure courtesy of Jay Famiglietti, UCCHM, UC Irvine

OPPORTUNITIES

The good news is that California can fill the gaps between water supply and use with a wide range of strategies that are cost-effective, technically feasible, more resistant to drought than the current system, and compatible with healthy river and groundwater basins. New supply options include greatly expanded water reuse and stormwater capture. Demand-management options include the adoption of more comprehensive efficiency improvements for cities and farms that allow us to continue to provide the goods and services we want, with less water. Efforts in these areas have been underway in California for decades, and laudable progress has been made, but much more can be done.

Efficiency, water reuse, and stormwater capture can provide effective drought responses in the near-term and permanent water-supply reliability benefits for the state. Moreover, by reducing reliance on imported water supplies and groundwater pumping, they can cut energy use and greenhouse emissions, reduce the need to develop costly new water and wastewater infrastructure, and eliminate pollution from stormwater and wastewater discharges. Finally, these strategies can also generate new jobs and provide new business opportunities.

To better understand the extent to which these alternatives could reduce pressure on the state's rivers and groundwater basins, the Pacific Institute, Natural Resources Defense Council, and Professor Robert Wilkinson from the University of California, Santa Barbara undertook a series of assessments of the potential for urban and agricultural water conservation and efficiency, water reuse, and stormwater capture. In particular, we evaluated the technical potential, i.e., the total water supplies and demand reductions that are feasible given current technologies and practices.[5] These measures are already being adopted in California and have been shown to be cost-effective compared to other water supply alternatives (Cooley et al. 2010; DWR, 2013b). The next section provides a short summary of the additional technical potential for each of these strategies.

Improving Agricultural Water-Use Efficiency

Agriculture uses approximately 80 percent of California's developed water supply (DWR, 2014b). As such a large user, it is heavily impacted by the availability and reliability of California's water resources. Moreover, agriculture can play an important role in helping the state achieve a more sustainable water future. California irrigators have already made progress in modernizing irrigation practices, but more can be done to promote long-term sustainable water use and ensure that agricultural communities remain healthy and competitive. Since 2000, several research studies—including two sponsored by the CALFED Bay-Delta Program and a third by the nonprofit Pacific Institute—have shown that there is significant untapped agricultural water-use efficiency potential in California (CALFED, 2000 and 2006; Cooley et al., 2009). Although the studies varied in their geographic scope and in their approach, the researchers came up with remarkably similar numbers, finding that agricultural water use could be reduced by 5.6 million to 6.6 million acre-feet per year, or by about 17 to 22 percent, while maintaining current irrigated acreage and mix of crops. As much as 0.6 million to 2.0 million acre-feet per year represent savings in consumptive use, which can then be allocated to other uses. The rest of the savings reflect reductions in the amount of water taken from rivers, streams, and groundwater, leading to improvements in water quality, instream flow, and energy savings, among other benefits. Additional water savings could be achieved by temporarily or permanently fallowing land or switching crop types, but these options were not evaluated here.

Improving Urban Water-Use Efficiency

Greater urban water conservation and efficiency can reduce unnecessary and excessive demands for water, save energy, reduce water and wastewater treatment costs, and eliminate the need for costly new infrastructure. Between 2001 and 2010, California's urban water use averaged 9.1 million acre-feet per year, accounting for about one-fifth of the state's developed water use (DWR, 2014b). By adopting proven technologies and practices, businesses can improve water-use efficiency by 30 to 60 percent. Residential users can improve home water-use efficiency by 40 to 60 percent by repairing leaks, installing the most efficient appliances and fixtures, and adopting landscape designs with less turf grass and more native and drought tolerant plants. In addition, water utilities can expand their efforts to identify and cut leaks and losses in underground pipes and other components of their distribution systems. Together, these savings could reduce urban water use by 2.9 million to 5.2 million acre-feet per year.

Greater Water Reuse

Water reuse is a reliable, local water supply that reduces vulnerability to droughts and other water-supply constraints. It can also provide economic and environmental benefits by reducing energy use, diversions from rivers and streams, and pollution from wastewater discharges. There is significant opportunity to expand water reuse in California. An estimated 670,000 acre-feet of municipal wastewater is already beneficially reused in the state each year (SWRCB and DWR, 2012). Onsite reuse—including the use of graywater—is also practiced across California, although data are not available to estimate the extent of reuse. We estimate that the water reuse potential in California, beyond current levels, ranges from 1.2 million to 1.8 million acre-feet per year, after taking into account efficiency opportunities. Approximately two-thirds of the reuse potential is in coastal areas where wastewater is discharged into the ocean or into streams that drain into the ocean. In these areas, expanding water reuse can provide both water-supply and water-quality benefits.

Expanding Stormwater Capture and Use

Municipalities used to manage stormwater by channeling it away from developed land and urban centers as quickly as possible. This approach reduces the amount of freshwater available for groundwater recharge and use, and it creates tremendous pollution problems with stormwater discharges to rivers, lakes, and ocean waters. As water resources have become increasingly constrained, there is new interest in capturing stormwater runoff as a sustainable source of supply (CNRA, 2014). In California, there are substantial opportunities to use stormwater beneficially to recharge groundwater supplies or for direct use for non-potable applications. Our assessment indicates that capturing stormwater from paved surfaces and rooftops in urbanized Southern California and the San Francisco Bay Area can increase average annual water supplies by 420,000 to 630,000 acre-feet or more each year, while also reducing both flooding and a leading cause of surface water pollution in the state.

Combined Water Supply and Demand Reductions

Together, these improvements in water conservation and efficiency, water reuse, and stormwater capture can provide 10.8 – 13.7 million acre-feet in new supplies and demand reductions. As shown in Figure 1, these savings can be realized throughout the state. There are, however, important regional differences. In the Central Valley and the Colorado River hydrologic region, for example, the majority of savings are from agriculture, although savings from other strategies are also available. In coastal areas, the majority of savings are in urban areas. Statewide, urban conservation and efficiency combined with water reuse and stormwater capture provide the equivalent in new supplies and demand reductions as agricultural efficiency (Table 1).

Along the coast and in areas that drain into a salt sink, these measures provide water supply and water quality benefits. In inland areas, some portion of the yield of these measures may already be used by a downstream user and thus do not constitute "new" supply. However, even in such locations, the measures described here can improve the reliability of water supplies, leave water instream for use by ecosystems, replace the need for potable water, and reduce pressure on the state's overtaxed rivers and groundwater basins.

Figure 2. Total water supply and demand changes with four drought response strategies, in thousand acre-feet per year, by hydrologic region

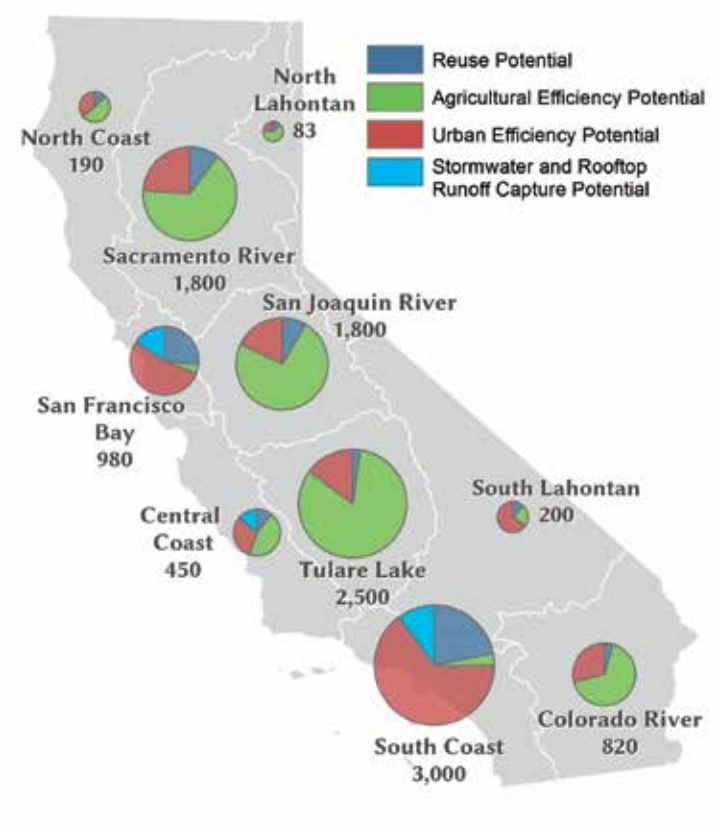


Table 1. Statewide water supply and demand changes with four drought response strategies

Strategy	Water Savings (million acre-feet per year)
Agricultural water conservation and efficiency	5.6 – 6.6
Urban water conservation and efficiency	2.9 – 5.2
Water reuse	1.2 – 1.8
Stormwater capture	0.4 – 0.6

Note: Stormwater capture was only examined in the San Francisco Bay Area and the South Coast. There is additional potential to capture stormwater in other regions of the state, although we did not evaluate that here. The values shown in this figure represent the midpoint of the ranges for each strategy.

CONCLUSIONS

We conclude that there is tremendous untapped potential to improve efficiency and augment supplies in California. Water efficiency, water reuse, and stormwater capture can provide 10.8 million – 13.7 million acre-feet of water in new supplies and demand reductions. These alternatives can provide both effective drought responses in the near-term and permanent water-supply reliability benefits for the state. Additionally, they can reduce energy use and greenhouse emissions, lower environmental impacts, and create new business and employment opportunities. Given the large potential and broad agreement about these strategies, state, federal, and local water agencies should move much more rapidly to implement policies to capture this potential.

California is reaching, and in many cases has exceeded, the physical, economic, ecological, and social limits of traditional supply options. We must expand the way we think about both "supply" and "demand"—away from costly old approaches and toward more sustainable options for expanding supply, including water reuse and stormwater capture, and improving water use efficiency. There is no "silver bullet" solution to our water problems, as all rational observers acknowledge. Instead, we need a diverse portfolio of sustainable solutions. But the need to do many things does not mean we must, or can afford, to do everything. We must do the most effective things first.

Identifying the technical potential to expand non-traditional supply options and increase water-use efficiency savings is just the first step in tackling California's water problems. Equally, if not more, important is adopting policies and developing programs to achieve those savings. A substantial body of law and policy already points the way to a more sustainable future for our state. For example, the California Constitution prohibits the waste of water. Likewise, the Brown Administration's California Water Action Plan supports local water projects that increase regional self-reliance and result in integrated, multi-benefit solutions. Many of these themes are also expressed in policy documents and recommendations from the California Urban Water Conservation Council, the Pacific Institute, the Association of California Water Agencies, the Delta Stewardship Council, the California Council on Science and Technology, the California Water Foundation, and others.

There is broad agreement on the value of improved efficiency, water reuse, and stormwater capture. The challenge is not a lack of knowledge or vision about what to do, but rather the urgent need for more effective implementation of strategies already known to work. Many innovative policymakers around the state have proposed new approaches to promote more widespread implementation of these strategies. We look forward to working with the Governor, agency heads, legislative leaders, water suppliers, and civic and business leaders to follow up with more specific actions for bringing the supply and demand for water in California into a sustainable balance.

References

Borchers, J.W., V. Kretsinger Grabert, M. Carpenter, B. Dalgish, and D. Cannon. 2014. *Land Subsidence from Groundwater Use in California*. Prepared by Luhdorff & Scalmanini Consulting Engineers.

California Natural Resources Agency (CNRA). (2014). *California Water Action Plan: Actions for Reliability, Restoration, and Resilience*. Final Draft. Sacramento, CA.

Cooley, H., J. Christian-Smith, P.H. Gleick, M.J. Cohen, M. Heberger. 2010. *California's Next Million Acre-Feet: Saving Water, Energy, and Money*. Pacific Institute, Oakland, California. 27 pages.

Delta Stewardship Council (DSC). (2013). *The Delta Plan*. Sacramento, CA. Accessed on 25 May 2014 at http://deltacouncil.ca.gov/sites/default/files/documents/files/DeltaPlan_2013_CHAPTERS_COMBINED.pdf.

Department of Water Resources (DWR). (2003). *California's Groundwater*. Bulletin 118. Sacramento, CA.

Department of Water Resources (DWR). (2013a). *Managing an Uncertain Future*. Volume 1, Chapter 5 of the California Water Plan Update. Bulletin 160. Sacramento, CA.

Department of Water Resources (DWR). (2013b). Introduction. Volume 3, Chapter 1 of the *California Water Plan Update*. Bulletin 160. Sacramento, CA.

Department of Water Resources (DWR). (2014a). *Groundwater Basins with Potential Water Shortages and Gaps in Groundwater Monitoring*. Public Update for Drought Response. Sacramento, CA.

Department of Water Resources (DWR). (2014b). *California Water Balances*, 1998-2010. California Department of Water Resources. Emailed to the author by Evelyn Tipton.

Famiglietti, J. (2014). Epic California drought and groundwater: where do we go from here? Water Currents. National Geographic Blog.

Hanak, Ellen, Jay Lund, Barton "Buzz" Thompson, W. Bowman Cutter, Brian Gray, David Houston, Richard Howitt, Katrina Jessoe, Gary Libecap, Josué Medellín-Azuara, Sheila Olmstead, Daniel Sumner, David Sunding, Brian Thomas, and Robert Wilkinson, 2012. *Water and the California Economy*. Public Policy Institute of California. http://www.ppic.org/main/publication.asp?i=1015

Hayden, A. and S. Rosekrans. 2004. *Quantification of Unmet Environmental Objectives in State Water Plan* 2003 using actual flow data for 1998, 2000, and 2001. California Water Plan Update. Accessed on 15 May 2014 at http://www.waterplan.water.ca.gov/docs/cwpu2009/0310final/v4c10a07_cwp2009.pdf.

Legislative Analyst's Office (LAO). (2013). Cal Facts 2013. Sacramento, California. Accessed on 8 May 2014 at http://www.lao.ca.gov/reports/2013/calfacts/calfacts_010213.aspx#Californias_Economy.

State Water Resources Control Board (SWRCB) and California Environmental Protection Agency (Cal EPA). (2010a). *Development of Flow Criteria for the Sacramento-San Joaquin Delta Ecosystem*. Prepared Pursuant to the Sacramento-San Joaquin Delta Reform Act of 2009. Accessed on 6 May 2014 at http://www.waterboards.ca.gov/waterrights/water_issues/programs/bay_delta/deltaflow/docs/final_rpt080310.pdf.

State Water Resources Control Board (SWRCB) and California Environmental Protection Agency (Cal EPA). (2010b). Appendix B. Draft Development of Flow Criteria for the Sacramento-San Joaquin Delta Ecosystem. Prepared Pursuant to the Sacramento-San Joaquin Delta Reform Act of 2009. Accessed on 6 May 2014 at http://www.waterboards.ca.gov/waterrights/water_issues/programs/bay_delta/deltaflow/docs/draft_report072010.pdf.

UC Center for Hydrologic Modeling (UCCHM). (2014). *Water Storage Changes in California's Sacramento and San Joaquin River Basins from GRACE: Preliminary Updated Results for 2003-2013*. UCCHM Water Advisory #1.

United States Fish & Wildlife Service (USFWS). (2001). *Tissue Residues and Hazards of Waterborne Pesticides for Federally Listed and Candidate Fishes of the Sacramento-San Joaquin River Delta*. Accessed on 28 May 2014 at http://www.fws.gov/pacific/ecoservices/envicon/pim/reports/Sacramento/SacramentoDelta.htm.

Footnotes

1 Water Code section 85086(c)(1): "For the purpose of informing planning decisions for the Delta Plan and the Bay Delta Conservation Plan, the board shall, pursuant to its public trust obligations, develop new flow criteria for the Delta ecosystem necessary to protect public trust resources."

2 See, e.g., page 5 of SWRCB and California EPA (2010a), recommending the general magnitude and timing of 75 percent of unimpaired Delta outflow from January through June, from approximately 30 percent in drier years to almost 100 percent in wetter years; 75 percent of unimpaired Sacramento River inflow from November through June, from an average of about 50 percent from April through June; and 60 percent of unimpaired San Joaquin River inflow from February through June, from approximately 20 percent in drier years to almost 50 percent in wetter years.

3 SWRCB and California EPA (2010b) at 180, Scenario B (2,258 thousand acre-feet (TAF) north-of-Delta delivery difference + 1,031 TAF south-of-Delta delivery difference = 1,609 TAF Vernalis flow difference = 4,898 TAF).

4 Of California's 515 alluvial groundwater basins, 169 are fully or partially monitored under the CASGEM Program and 40 of the 126 High and Medium priority basins are not monitored under CASGEM. The greatest groundwater monitoring data gaps are in the Sacramento, San Joaquin River, Tulare Lake, Central Coast, and South Lahontan hydrologic regions (DWR 2014a).

5 The technical potential estimated in these analyses is based on current use patterns and does not include population and economic growth, or changes in the total acreage or types of crops grown in the state. Increased population can result in increased demand, and these tools can help offset that growth. We do not examine the economic or market potential of these alternatives.

Authors and Acknowledgements

The lead author of this report is Peter Gleick, with additional contributions by Heather Cooley, Kate Poole and Ed Osann. Support for this work was provided by the Pisces Foundation. Numerous individuals provided comments on this report; we thank them for their input.

Natural Resources Defense Council
40 West 20th Street
New York, NY 10011
212 727-2700
Fax 212 727-1773

Beijing

Chicago

Los Angeles

Bozeman

San Francisco

Washington, D.C.

www.nrdc.org

www.nrdc.org/policy
www.facebook.com/nrdc.org
www.twitter.com/nrdc

Pacific Institute
654 13th Street, Preservation Park
Oakland, CA 94612, USA
Phone: 510-251-1600
Fax: 510-251-2203

www.pacinst.org
www.californiadrought.org

www.facebook.com/PacificInstitute
www.twitter.com/PacificInstitut

Printed on recycled paper

Attachment 16

The New York Times | https://nyti.ms/1n9cflB

Opinion | EDITORIAL

Saving Water in California

By THE EDITORIAL BOARD JULY 9, 2014

California is in the third year of its worst drought in decades. But you wouldn't know it by looking at how much water the state's residents and businesses are using. According to a recent state survey, Californians cut the amount of water they used in the first five months of the year by just 5 percent, far short of the 20 percent reduction Gov. Jerry Brown called for in January. In some parts of the state, like the San Diego area, water use has actually increased from 2013.

Without much stronger conservation measures, the state, much of which is arid or semiarid, could face severe water shortages if the drought does not break next year. Los Angeles recently recorded its lowest rainfall for two consecutive years, and climate change will likely make drought a persistent condition, according to the National Climate Assessment report published in May.

Yet, even now, 70 percent of water districts have not imposed reasonable mandatory restrictions on watering lawns and keeping backyard pools filled. The State Water Resources Control Board is to consider placing restrictions on some outdoor water uses like washing paved surfaces at a meeting on July 15.

California's agriculture sector is the largest in the country, and it accounts for about 80 percent of the state's water use. Even a small percentage reduction in the fields could have a sizable effect on total water consumption.

A recent report by the Pacific Institute and the Natural Resources Defense Council estimates that agricultural water use could be reduced by up to 22 percent if farmers more

carefully scheduled the watering of crops based on weather and soil conditions and if they used the drip irrigation systems that deliver water directly to the roots of plants. Some progress has been made. About 38 percent of California farmland was irrigated by more efficient systems in 2010, up from 15 percent in 1991. But far too many farmers still irrigate by flooding their fields.

In terms of urban conservation, the report shows that homes and businesses could reduce water use by up to 60 percent by using it more efficiently, recycling and reusing water and capturing more rainwater. Some efficiency improvements are simple and could be done quickly, like installing water meters at all homes and businesses. Currently, about 250,000 water-utility customers, most of them in the Central Valley, have no meters and are charged a flat monthly fee regardless of how much water they use — a practice that invites waste.

Other changes will take longer to carry out but could have a big impact. For instance, Santa Cruz's municipal water utility imposes water "budgeting" under which it determines how much water each home needs based on where it is and the number of people in the household. Customers who use more than their budgeted amount must pay higher rates for extra water used. This approach has helped Santa Cruz cut water use by about 30 percent since 1987.

Other government programs have been effective, too, and deserve broader adoption. The Los Angeles Department of Water and Power last month began paying people $3 for every square foot of grass they replace with landscaping that requires little or no water under a "cash in your lawn" program, up from $2 previously; residents can claim up to $6,000 under that program. The department says it has paid to have 8 million square feet of lawn removed since the program started in 2009.

Finally, state officials need to act with a much greater urgency. Earlier this year, the State Legislature set aside nearly $700 million for emergency drought relief, but 90 percent of that money has yet to be spent. Mr. Brown's administration should think a lot bigger than emergency aid aimed at a single drought. The state must focus on longer-term policies that encourage people to alter their lifestyles and businesses to change how they operate.

Meet The New York Times's Editorial Board »

A version of this editorial appears in print on July 10, 2014, on Page A26 of the New York edition with the headline: Saving Water in California.

Attachment 17

NATURAL RESOURCES DEFENSE COUNCIL

Testimony of David D. Doniger
Policy Director and Senior Attorney, Climate and Clean Air Program
Natural Resources Defense Council

Hearing on the American Energy Initiative: A Focus on EPA's Greenhouse Gas Regulations

Subcommittee on Energy and Power
Committee on Energy and Commerce
House of Representatives
June 19, 2012

Summary

- Nearly 2 million Americans – more than double the previous record – have already raised their voices in comments to support EPA's proposed carbon pollution standard for power plants. More than 60 percent of Americans support EPA's setting carbon pollution standards according to a recent bipartisan poll conducted for the American Lung Association.

- Carbon pollution is imposing staggering health and environmental costs, including by contributing to more severe heat waves and worsened smog pollution and by fueling increasingly extreme weather that takes lives and causes billions of dollars in property damage each year. June 2011-May 2012 was the warmest 12-month stretch ever in the U.S.

- Two Supreme Court decision, *Massachusetts v. EPA* and *American Electric Power v. Connecticut*¸ confirm that it is EPA's job under the Clean Air Act as Congress enacted it to protect the American people from carbon pollution from both cars and power plants.

- By proposing standards for new power plants under Section 111(b) of the Clean Air Act, EPA is simply following the law and the science. Power plants are the largest U.S. source of greenhouse gases: 2.3 billion metric tons per year of CO_2 emissions, approximately 40 percent of the U.S. total.

- NRDC supports EPA's decision to establish a single category including all new plants, however fueled, that perform the same function of base-load and intermediate-load power generation. Owners and operators have the flexibility to choose among these technologies when building new plants to serve this function.

- The proposed new source standard recognizes that the market has already turned away from building new conventional coal plants due low-cost natural gas, strong growth in wind and solar power, big opportunities to improve energy efficiency, and even the potential for nuclear power. Analysts from government, the power industry, and the financial world all forecast that we will meet electricity needs over the next two decades without constructing new coal-fired plants.

- Thus, despite all the rhetoric and scape-goating, this standard will impose no additional costs on the industry or on electricity rate-payers and will have no adverse impact on jobs.

- NRDC agrees that CCS-equipped coal-fired plants are technically feasible today and can meet the proposed standard. NRDC supports proposed provisions to facilitate construction of CCS-equipped plants. NRDC has long supported well-designed legislative measures to accelerate the deployment of CCS, including tens of billions of dollars of support that would have been provided to power companies for adopting CCS under the climate and energy legislation considered in the last Congress.

- EPA needs to move forward to start the joint Federal-state process of cutting the 2.3 billion tons of dangerous carbon pollution from the existing fleet of power plants under Section 111(d). It is just plain false to claim that existing coal plants will be required to meet the new plant standard. The criteria and procedures for new and existing plants are different. EPA and the states must set existing source standards that are achievable and affordable. NRDC believes significant, cost-effective reductions can and should be made within that legal framework.

Thank you Chairman Whitfield and Ranking Member Rush for the opportunity to testify on behalf of the Natural Resources Defense Council about the Environmental Protection Agency's proposed carbon pollution standard for new electric power plants, and related actions to carry out the agency's responsibilities under the Clean Air Act to address the pollution that drives dangerous climate change. Founded in 1970, NRDC is a national nonprofit environmental organization of scientist, lawyers, and environmental specialists with more than 1.3 million members and online activists, served from offices in New York, Washington, Chicago, San Francisco, Los Angeles, and Beijing. I am policy director of NRDC's Climate and Clean Air Program, and our principal lawyer on climate change matters. I have been with NRDC twice, from 1978 through 1992 and from 2001 to the present. In the 1990's I served as director of climate change policy in the EPA Office of Air and Radiation.

Although the period for public comment has not yet finished, already nearly two million citizens across this country – more than double the previous record number in the EPA's history – have raised their voices in comments to support action under the Clean Air Act to curb the dangerous carbon pollution from our fleet of power plants.

This record outpouring should come as no surprise, since public polling consistently shows the American people supports the Environmental Protection Agency's doing its job, under the laws that Congress enacted, to protect their health and their future. For example, 60 percent of the American people support EPA's setting standards for carbon dioxide pollution, even after hearing the arguments against that many of you are making today, according to the most recent bipartisan poll conducted for the American Lung Association.[1]

Americans in record numbers are concerned, because scientists tell us that carbon pollution is imposing, and will continue to impose, staggering health and environmental costs. The health consequences include contributing to more severe heat waves and worsened smog pollution, which

[1] http://www.prnewswire.com/news-releases/american-lung-association-bipartisan-poll-shows-strong-public-support-for-lifesaving-clean-air-act-116319864.html.

trigger more asthma attacks and other life-threatening illnesses. Carbon pollution is driving climate change that is fueling increasingly extreme weather, including more extreme heat, more extreme precipitation, devastating tropical storms, rising sea levels and more severe coastal flooding, and many other threats to life, limb, and property.[2] Americans had extraordinary personal experiences with extreme weather last year. Across the country, 2011 gave us 3,251 broken monthly weather records -- so many extreme events that NRDC created an online map tool to track them and the destruction they caused.[3] 2012 is off to another record-smashing start: March 2012 was the hottest March in the contiguous US since record-keeping began back in 1895.[4] May 2012 marked the end of the warmest 12-month stretch ever in the US.[5]

Looking back over the past decade, case studies of six extreme weather events – heat waves, wildfires, floods, smog episodes, hurricanes, and disease outbreaks – yielded health-related costs of more than $14 billion.[6] A new study by the Rocky Mountain Climate Organization and NRDC shows that the number of extreme rainstorms – storms dumping more than three inches of rain in a day – has doubled over the last 50 years in eight Midwestern states, causing huge flooding losses.[7]

---

[2] IPCC, 2012: Summary for Policymakers. In: Managing the Risks of Extreme Events and Disasters to Advance Climate Change Adaptation [Field, C.B., V. Barros, T.F. Stocker, D. Qin, D.J. Dokken, K.L. Ebi, M.D. Mastrandrea, K.J. Mach, G.-K. Plattner, S.K. Allen, M. Tignor, and P.M. Midgley (eds.)]. A Special Report of Working Groups I and II of the Intergovernmental Panel on Climate Change. Cambridge University Press, Cambridge, UK, and New York, NY, USA, pp. 3-21.

[3] NRDC's *Extreme Weather Map 2011* website is available at: www.nrdc.org/extremeweather and on NRDC's *Climate Change Threatens Health* webpages at: www.nrdc.org/climatemaps. Data for the map was taken from the National Oceanic and Atmospheric Administration-National Climatic Data Center (NOAA-NCDC); the methods used to develop the map are described at: http://www.nrdc.org/health/extremeweather/methods.asp (updated Feb. 2012).

[4] NOAA-NCDC (2012) website at: http://www.ncdc.noaa.gov/temp-and-precip/time-series/index.php?parameter=tmp&month=3&year=2012&filter=1&state=110&div=0 ("Contiguous U.S. Temperature: March 1895-2012").

[5] NOAA-NCDC (2012), http://www.ncdc.noaa.gov/sotc/national/2012/5 .

[6] Knowlton, *et al*., "Six Climate Change–Related Events In The United States Accounted For About $14 Billion In Lost Lives And Health Costs," *Health Affairs*, **30**:11, pp. 2167-76 (Nov. 2011). *See also* NRDC, "Health and Climate Change: Accounting for Costs," Nov. 2011, http://www.nrdc.org/health/accountingforcosts/files/accountingcosts.pdf (attached for the record).

[7] Rocky Mountain Climate Organization & NRDC, "Double Trouble: More Midwestern Extreme Storms," May, 2012, http://www.rockymountainclimate.org/images/DoubledTroubleHigh.pdf.

The Supreme Court's landmark 2007 ruling in *Massachusetts v. EPA*[8] confirmed that greenhouse gases, just like any other chemicals released into the air, are "air pollutants" under the Clean Air Act. The Court held that EPA must make a science-based determination whether these pollutants may reasonably be anticipated to endanger public health or welfare, and if so, that EPA must set standards to their emissions under the Clean Air Act. EPA made that endangerment finding in 2009, based on a mountain of scientific evidence that demonstrates that carbon dioxide and other heat-trapping pollutants are already harming, and will continue to harm, the health and well-being of our families, our children, and our communities. You have heard about EPA's other initial steps – the clean vehicle standards and permitting requirements for the biggest new industrial facilities – from Daniel Weiss of the Center for American Progress on the first panel. I will concentrate on the carbon pollution standard proposed in April for new power plants.

The Supreme Court spoke a second time specifically addressing power plants, in June 2011 in *American Electric Power v. Connecticut*,[9] confirming that it is EPA's job to protect the American people from power plants' dangerous carbon emissions by setting standards under Section 111 of the Clean Air Act. The "new source performance standard" that EPA has proposed for new power plants under Section 111(b) is a critical step towards providing that protection.

Power plants have long topped the list of categories of industrial stationary sources that contribute significantly to air pollution that endangers public health and welfare. Fossil fuel-fired power plants are responsible for more than 2.3 billion metric tons per year of CO_2 emissions, approximately 40 percent of total U.S. CO_2, and more than a third of all U.S. greenhouse gas emissions. American power plants account for nearly 10 percent of *global* CO_2 emissions. By any standard, power plants contribute significantly to dangerous greenhouse gas air pollution. By proposing standards for new power plants under Section 111(b) of the Clean Air Act, EPA is simply following the law and the science. Its proposal

[8] 549 U.S. 497 (2007).
[9] 131 S.Ct. 2527 (2011).

to set the first national limits on carbon pollution from new power plant, which applies only to new plants, not existing or modified ones, is long overdue.

NRDC supports EPA's determination to establish a single category that includes both natural gas-fired generating units and coal-fired generating units. As EPA has found, these units perform the same function of base-load and intermediate-load power generation, and prospective owners and operators have the flexibility to choose among these technologies when building new plants to serve this function. Consequently, NRDC also supports setting a single emissions-rate standard applicable to all new plants in the category. EPA has proposed 1000 lbs/MWh standard and a range of levels around this mark. NRDC supports setting the new source standard somewhat below 1000 lbs/MWh because modern new natural gas combined cycle plants can meet such levels at no additional cost. New coal-fired plants equipped with carbon capture and storage technology (CCS) can also meet that level, especially with the 30-year averaging provisions that EPA has proposed.

There is no truth to claims that grouping all new plants that perform the same function – whether natural gas- or coal-fired – in the same category under the proposed new source standard is a "de facto ban" on constructing new coal-fired plants, nor to claims that the standard will cause lost jobs and higher utility bills. These are phony arguments. The proposed new source standard actually will impose no additional costs on the industry or on electricity rate-payers and will have no adverse impact on jobs.

The reason is that market realities have already driven decisions on new power plants away from building new conventional coal plants. As Brookings senior economist Peter Wilcoxen explained in April: "To put it simply: the life-cycle costs of coal-fired power are considerably higher than gas-fired power. This is not a theoretical matter: over the last decade, the electric power sector has responded by adding more than about 200 gigawatts of gas-fired capacity and about 2 gigawatts of coal. The US now has considerably more gas-fired capacity than coal-fired capacity and low gas prices will accelerate

that trend even without the EPA decision." He continued: "Finally, because it only rules out an expensive option that wouldn't have been used anyway, the EPA rule will have no significant effect on electricity prices."[10]

Analysts from government departments, the power industry, and the financial world all agree in forecasting that the nation will meet its electricity needs over the next two decades without constructing new coal-fired plants.[11] Power companies simply aren't planning to build new coal plants due to the availability of low-cost natural gas, strong growth in wind and solar power, big opportunities to improve energy efficiency, and even the potential for nuclear power. For example, the country's largest current CO2 emitter, American Electric Power, stated that the proposed rule "doesn't cause immediate concern" for the company. "We don't have any plans to build new coal plants," said AEP spokesperson Melissa McHenry in March. She continued, "Any additional generational plants we'd build for the next generation will be natural gas."[12] And Jim Rogers, CEO of Duke Energy, operating in the Carolinas, Indiana, Kentucky, and Ohio, told the National Journal in February: "We're not going to build any coal plants in any event. You're going to choose to build gas plants every time, regardless of what the rule is."[13]

These market forecasts are robust. EPA's sensitivity analyses in the Regulatory Impact Analysis show that power companies will not choose to construct any new conventional coal-fired plants before 2030 even if natural gas becomes *4-5 times more costly than it is today and power demand increases faster than expected*.[14]

---

[10] http://mediamatters.org/research/201204020012.

[11] See sources cited by Lashof, "Financial Analysts, Private Economists, and Government Forecasters All Agree: Market Realities, Not EPA, Driving New Power Plants Away from Coal," April 2012, http://switchboard.nrdc.org/blogs/dlashof/financial_analysts_private_eco.html.

[12] National Journal, Government Executive (Mar. 27, 2012), http://www.govexec.com/oversight/2012/03/first-major-climate-regs-obama-epa-sure-stir-political-debate/41580/

[13] National Journal, Need to Know: Energy (Feb. 2, 2012).

[14] EPA Regulatory Impact Analysis for the Proposed Standards of Performance for Greenhouse Gas Emissions for New Stationary Sources: Electric Utility Generating Units, Chapter 5 (March 2012), http://epa.gov/carbonpollutionstandard/pdfs/20120327proposalRIA.pdf.

The proposed new source standard reinforces what most power company executives and investors already understand – that carbon pollution and climate change are serious concerns, and that if and when underlying market economics support a comeback for new coal-fired power plants, they will need to be designed with CCS.

The nation's utilities also have huge money-saving opportunities to shift investments to energy efficiency, which is cheaper than power from either coal or gas-fired plants. By doing so they will create hundreds of thousands of jobs, since it takes a lot more people to upgrade homes, offices, and factories with better insulation and lighting, high performance heating and cooling systems, and more efficient appliances and equipment. Between 2007 and 2011, American electric efficiency budgets more than doubled, from $2.7 billion to $6.8 billion, but they have only scratched the surface of the cost-effective efficiency resource that is available to us.[15] According to McKinsey & Co., we could save $1.2 trillion on our national energy bill while creating almost 1 million jobs if we captured all of this resource.[16]

NRDC supports provisions EPA has proposed to facilitate construction of coal-fired plants equipped with CCS. NRDC agrees that CCS-equipped plants are technically feasible today and can be built – and are being built today[17] – even under current market conditions with subsidies provided under federal law. Further, NRDC agrees with EPA's assessment that further experience with CCS can bring costs down. I will also note that NRDC has long supported well-designed legislative measures to accelerate the deployment of CCS, including tens of billions of dollars of support that would have been provided to power companies for adopting CCS under the climate and energy legislation considered in the last Congress.

---

[15] Consortium for Energy Efficiency, "Energy Efficiency Picture Emerges," http://www.cee1.org/ee-pe/2011AIR.php3.

[16] McKinsey & Co. , "Electric Power and Natural Gas, Unlocking Energy Efficiency in the U.S. Economy," 6 and 118, McKinseyGlobal Energy and Materials, July 2009, http://www.mckinsey.com/client_service/electric_power_and_natural_gas/latest_thinking/unlocking_energy_efficiency_in_the_us_economy.

[17] For example, Mississippi Power Company's Kemper County Plant Ratcliffe is now under construction and will capture and sequester 65 percent of its carbon dioxide emissions.

As already mentioned, EPA's proposed standards apply to new plants only, not existing or modified ones. Despite some rather clear statutory language to the contrary, EPA has even proposed to treat as existing plants a set of so-called "transitional" coal-fired plants that have permits but not commenced construction yet, provided they do so within a year. Like dozens of other proposals for new coal-fired capacity that have been abandoned because of market realities over the past years, many of these plants probably will not go forward because they lack financing and can't meet other, non-Clean Air Act legal requirements. Indeed, at least one of the transitional plants has already been dropped. Tenaska, which had proposed a coal-fired plant for southern Illinois has dropped it in favor of a new natural gas plant. Further, the majority owner of the proposed Holcomb 2 project, Tri-State Generation and Transmission, Inc., has published and filed with the Colorado Public Utilities Commission a final Electric Resource Plan stating that it has no need for any new coal-fired power until at least 2027. Tri-State's extensive resource planning modeling demonstrated that future demand could be met with a combination of cleaner alternatives, such as demand side management and renewable generation resources.[18] When questioned, Tri-State has advised the press that it planned to delay construction of Holcomb 2.

Going forward, EPA also needs to issue standards and guidelines under Section 111(d) of the Clean Air Act to start the joint Federal-state process of cutting the 2.3 billion tons of dangerous carbon pollution from the existing fleet of power plants. Another false claim you will hear is doing so will wipe out existing coal plants by requiring them to meet the same standard that EPA has proposed for new plants. But this is not what the Act requires. The criteria and procedures under Sections 111(b) and 111(d) are different, and under the statute EPA and the states share the job of setting performance standards for existing sources. EPA and the states have a legal obligation to set standards that are

[18] Integrated Resource Plan / Electric Resource Plan for Tri-State Generation and Transmission Associate, Inc., Submitted to Western Area Power Authority, Colorado Public Utilities Commission (Nov. 2010). Tri-State Generation and Transmission Associate, Inc., Resource Planning Presentation (June 10, 2010).

achievable and affordable. Within that legal framework, NRDC believes significant, cost-effective reductions in the heat-trapping CO_2 from existing power plants can and must be made, and EPA must begin that process forthwith.

In conclusion, the proposed carbon pollution standard for new power plants is another important step that EPA has taken under President Obama to clean up and modernize the nation's two most polluting sectors – the power plants that provide our electricity, and the motor vehicles that move us around. When the second round of carbon pollution and fuel economy standards for new cars and light trucks are finalized later this summer, they will cut carbon pollution in half and double miles per gallon, saving car-owners thousands of dollars at the pump and dramatically cutting our oil dependence. Because of these standards, and the ones set for heavy duty trucks, America's oil use is finally falling, and is expected to continue falling as far as the eye can see, even as oil production grows.

Scientists and the public agree overwhelmly that it is time to start protecting our families and the planet from the clear harm carbon pollution is causing. We owe it to our children to act now. Denial won't change the facts about carbon. It won't keep rising seas from eroding coastal property, just like it won't stop the wind from carrying pollution from one state to the next, mercury from being a brain poison, or soot from lodging in our lungs. Cleaning up pollution shouldn't be about politics. It's about fulfilling the promise to our families and our children that we will protect their health and their future from dangerous air pollution.

Attachment 18

Program

World Business Summit on Climate Change
Shaping the sustainable economy
Copenhagen, 24-26 May 2009

COPENHAGEN CLIMATE COUNCIL
Global partnership for a better climate

A Monday Morning Initiative

Sunday 24 May
Highlighting critical issues.

09:30- **REGISTRATION**

12:30-13:30 **LUNCH**

13:30-14:00
Plenary hall

OPENING CEREMONY (DOORS WILL CLOSE AT 13.29)
Welcome to the World Business Summit on Climate Change.
Opening address by
Ban Ki-moon, *Secretary-General, United Nations*

H.M.Q. Margrethe II of Denmark and H.R.H. The Prince Consort

Tim Flannery, *Scientist and Author; Chairman of the Copenhagen Climate Council*
Erik Rasmussen, *Chief Executive Officer, Monday Morning; Founder of the Copenhagen Climate Council*

H.M.Q. Margrethe II of Denmark and H.R.H. the Prince Consort will oversee the opening. Due to protocol reasons H.M.Q. and H.R.H. must be the last persons to enter the plenary hall. We kindly ask all participants to be seated well in advance.

14:00-14:25 **KEYNOTE ADDRESS** ■
Al Gore, *former US Vice President*
Introduced by
Lise Kingo, *Executive Vice President and Chief of Staffs, Novo Nordisk*

14:25-16:00
Plenary hall

SHAPING THE NEW GREEN ECONOMY
Interactive debate ■
The international community is facing the twin challenges of dealing with the most serious global economic crisis in decades and negotiating an ambitious agreement on climate change. How can these two challenges be turned into opportunity? What policies, incentives and investments will most effectively stimulate low-carbon growth? What are the pathways to a sustainable, global economy?
Indra Nooyi, *Chairwoman and Chief Executive Officer, PepsiCo*
Fu Chengyu, *Chief Executive Officer, China National Offshore Oil Corporation*
Philippe Joubert, *President, Alstom Power*
Lars G. Josefsson, *President and Chief Executive Officer, Vattenfall*
Walter B. Kielholz, *Chairman, Swiss Re*
Alan Salzman, *Chief Executive Officer, Vantage Point Venture Partners*
Ditlev Engel, *Chief Executive Officer, Vestas*
Masamitsu Sakurai, *Chairman, Ricoh*
Carl-Henric Svanberg, *Chief Executive Officer, Ericsson*
Girish S. Paranjpe, *Joint-Chief Executive Officer, Wipro*
Sultan Al Jaber, *Chief Executive Officer, Masdar*
Li Zhengmao, *Executive Board Member, China Mobile*
Moderated by
Geoff Cutmore, Anchor, CNBC

16:00-16:30 **BREAK**

16:30-16:45
Plenary hall

SPECIAL ADDRESS

Dr. R. K. Pachauri, *Director General, TERI; Chairman, Intergovernmental Panel on Climate Change*
In conversation with
Katherine Richardson, *Vice Dean, University of Copenhagen*

16:45-17:00
Plenary hall

SPECIAL SESSION: AVIATION

Despite progressively more efficient operations, emissions attributable to international aviation represent 2% of the global total and continue to rise. Absent a global framework, regional measures are being implemented that display promise but also raise concerns related to fairness and evasion. Can 2009 deliver on the promise of a global framework to address aviation emissions?
Giovanni Bisignani, *Chief Executive Officer, IATA*
Moderated by
Adam Aston, *Energy and Environment Editor, BusinessWeek*

17:00-18:00
Plenary hall

GETTING TO COPENHAGEN

Panel discussion

We are at a critical juncture, just six months before political leaders will gather at the UN Climate Change Conference (COP15) in Copenhagen to negotiate an ambitious agreement on climate change. What are the critical challenges and stumbling blocks on the road to Copenhagen? How can the business community support the policy process leading up to COP15 – and beyond?
Connie Hedegaard, *Minister of Climate and Energy, Denmark*
Xie Zhenhua, *Vice Chairman, National Development and Reform Commission, China*
Marthinus van Schalkwyk, *Minister of Environmental Affairs and Tourism, South Africa*
Erik Solheim, *Minister of the Environment and International Development, Norway*
Moderated by
Orville Schell, *Director, Center on U.S.-China Relations, Asia Society*

18:00-18:30

TRANSPORTATION TO RECEPTION

18:30-20:00

RECEPTION AT THE COPENHAGEN CITY HALL
Hosted by the City of Copenhagen
Klaus Bondam, *Deputy Mayor, City of Copenhagen*

INTERACTIVE DEBATE. Featuring key government officials, Chief Executive Officers, opinion leaders and experts interactive debates are engaging and dynamic sessions that involve all participants in discussing the broad issues on the Summit agenda and how to implement sustainable solutions.

WORKING GROUP. Guided by a skilled facilitator, working groups are designed to ensure the highest level of interaction between participants, with a view to sharing experiences, debating lessons learned and creating collaborative solutions to complex problems.

KEYNOTE AND SPECIAL ADDRESS. These short interventions provide a fresh perspective and a personal view on climate change from distinguished individuals.

PANEL DISCUSSION. These sessions are high-level panel discussions in plenary, where heads of state, Chief Executive Officers and other thought leaders high-light critical issues and new insights to inform the Summit.

Monday 25 May
Showcasing innovative solutions.

07:00- **REGISTRATION**

08:30-09:40 **INNOVATIVE BUSINESS PERSPECTIVES ON THE CLIMATE CHALLENGE**
Plenary hall *Panel discussion*
Meeting the climate challenge will require innovative approaches from businesses of all sectors and geographies. How can we engage partners, suppliers and consumers in developing and implementing new solutions? How can we involve some of the world's least privileged people in creating sustainable change?
Adam Werbach, *Chief Executive Officer, Saatchi & Saatchi S*
Sir Martin Sorrell, *Chief Executive Officer, WPP*
Paul Polman, *Chief Executive Officer, Unilever*
Jacqueline Novogratz, *Chief Executive Officer, Acumen Fund*
Harish Hande, *Co-founder and Managing Director, SELCO Solar Light*
Moderated by
Rick Duke, *Director, Center for Market Innovation, Natural Resources Defense Council*

09:40-10:00 **KEYNOTE ADDRESS**
Plenary hall **José Manuel Barroso,** *President, European Commission*
Introduced by
Anders Eldrup, *Chief Executive Officer and President, DONG Energy*

10:00-10:30 **BREAK**

10:30-12:30 **WORKING GROUPS IN PARALLEL #1**
The morning sessions will showcase solutions and experiences, presented by CEOs of leading global companies. The following topics will be addressed in working groups:
Technology push, ***Aud. 12***
Technology collaboration, ***Room BV1***
Financing the transition to a low-carbon economy, ***Room BV5***
Energy efficiency, ***Aud. 11***
Carbon market, ***Room 18 + 19***
Forestry and sustainable land use, ***Room 21***
Adapting to the effects of climate change, ***Room 20***
Measurement and progress, ***Room 17***
Value chain, ***Aud. 10***

12:30-14:00 **LUNCH**

14:00-15:45 **WORKING GROUPS IN PARALLEL #2**

The afternoon sessions will address policy incentives and public-private partnerships. What will it take to achieve rapid scaling-up of best practices? How can business and governments work together to make the transition to a low-carbon, sustainable economy? The following topics will be addressed in working groups:

Technology push, *Aud. 12*
Technology collaboration, *Room BV1*
Financing the transition to a low-carbon economy, *Room BV5*
Energy efficiency, *Aud. 11*
Carbon markets, *Room 18 + 19*
Forestry and sustainable land use, *Room 21*
Adapting to the effects of climate change, *Room 20*
Value chain, *Aud. 10*

15:45-16:15 **BREAK**

16:15-17:40 Plenary hall

RAPID TRANSFORMATION TO A LOW-CARBON ECONOMY: WHAT WILL IT TAKE?

Panel discussion

The entrepreneurial drive of business coupled with policies to facilitate large-scale investment in clean technologies and infrastructure can ensure rapid transformation to a low-carbon economy. But what mechanisms, policy instruments, metrics and new structures will be required to accelerate transformation?

Tony Hayward, *Group Chief Executive, BP*
Björn Stigson, *President, World Business Council for Sustainable Development*
Alan Salzman, *Chief Executive Officer, Vantage Point Venture Partners*
Frank Appel, *Chief Executive Officer, Deutsche Post*
Samuel A. DiPiazza, Jr., *Chief Executive Officer, PricewaterhouseCoopers*
Rob Morrison, *Chairman, CLSA Asia-Pacific Markets*
Steve J. Lennon, *Managing Director, Eskom*
Lise Kingo, *Executive Vice President and Chief of Staffs, Novo Nordisk*
Moderated by
Steve Howard, *Chief Executive Officer, The Climate Group*
With reflections from
Lord Michael Jay, *Globe International Advisory Board member*

17:40-18:00 Plenary hall

SPECIAL ADDRESS

Cate Blanchett, *Artistic Co-Director, Sydney Theatre Company*
Introduced by
Tim Flannery, *Chairman, Copenhagen Climate Council*

18:00-18:30 **TRANSPORTATION TO DINNER**

18:30-23:00 **OFFICIAL DINNER AT THE DANISH NATIONAL ARTGALLERY**

Attachment 19

NRDC
THE EARTH'S BEST DEFENSE

NATURAL RESOURCES DEFENSE COUNCIL

Arsenic and Old Laws

A Scientific and Public Health Analysis of Arsenic Occurrence in Drinking Water, Its Health Effects, and EPA's Outdated Arsenic Tap Water Standard

---

This February 2000 report analyzes data collected by water systems in 25 states between 1980 and 1998 and compiled by the U.S. Environmental Protection Agency. The study finds that millions of Americans drink tap water from systems that have been shown to contain arsenic, a known toxin and carcinogen, at average levels that pose unacceptable cancer risks. This report includes a summary of the adverse health effects of arsenic in drinking water by Dr. Paul Mushak, an eminent expert on the subject, based upon a 1999 National Academy of Sciences report. The report also contains detailed recommendations on what the EPA and water systems should do to reduce arsenic in drinking water and safeguard the health of the American public.

TABLE OF CONTENTS

Check the map

For an overview of the geographic distribution of arsenic problems in 25 states

For printed copies of this report, see our Publications List.

Related NRDC Pages
FAQ

NRDC
THE EARTH'S BEST DEFENSE

NATURAL RESOURCES DEFENSE COUNCIL

Arsenic and Old Laws

A Scientific and Public Health Analysis of Arsenic Occurrence in Drinking Water, Its Health Effects, and EPA's Outdated Arsenic Tap Water Standard

Top of Report

EXECUTIVE SUMMARY AND RECOMMENDATIONS

FINDINGS

Arsenic in drinking water poses a significant public health risk in the United States. According to our most conservative analysis of new EPA data covering only 25 states, at least 34 million Americans in over 6,900 communities drank tap water supplied by systems containing arsenic, a known toxin and carcinogen, at average levels that pose unacceptable cancer risks.[1] Our "best" estimate, based on what we believe to be the most reasonable (but less conservative) analytical techniques, indicates that 56 million Americans in over 8,000 communities in those 25 states drank water with arsenic at these risky levels.[2]

These newly public figures are based on more than 100,000 arsenic samples collected from 1980 to 1998 by more than 24,000 public water systems in 25 states, which were then compiled by the U.S. Environmental Protection Agency (EPA). The Natural Resources Defense Council (NRDC) obtained the data under the Freedom of Information Act and analyzed them. While arsenic levels can vary with time, when considering cancer risk, the average levels generally are of primary concern. For this reason, NRDC calculated average arsenic levels in the systems evaluated. Because data were available for only half of the states in the nation, these are likely to be significant underestimates of the total U.S. population exposed to arsenic in tap water.

NRDC also has generated maps for this report showing the geographic distribution of arsenic problems for all 25 reporting states. This marks the first time that EPA□s drinking water database has been publicly analyzed using a Geographic Information System (GIS) to generate maps of drinking water problems.

This report includes a summary of the adverse health effects of arsenic in drinking water by an eminent expert on the subject, based upon a 1999 National Academy of Sciences (NAS) report and a review of peer-reviewed literature. The NAS report and other scientific literature discussed here have concluded that arsenic in drinking water is a known cause of bladder, lung, and skin cancer. In addition, the NAS report and many previous studies have found that arsenic in drinking water may also cause kidney and liver cancer.

Arsenic□s known noncancer toxic effects include toxicity to the central and peripheral nervous systems, heart and blood vessel problems, and various precancerous lesions on the skin, such as hyperkeratosis (a pronounced scaly skin condition) as well as changes in pigmentation. The NAS report and peer-reviewed animal studies have found that arsenic may also cause birth defects and reproductive and other problems, although some of these effects are less documented than arsenic's cancerous, skin, nervous, and cardiovascular effects.

The NAS concluded in 1999 that EPA□s 57 year-old arsenic standard for drinking water of 50 parts per billion (ppb), set in 1942 before arsenic was known to cause cancer, "does not achieve EPA□s goal for public health protection and, therefore, requires downward revision as promptly as possible" (NAS, 1999, p. 9). In fact, the academy said that drinking water at the current EPA standard "could easily" result in a total fatal cancer risk of 1 in 100 -- about a 10,000 times higher cancer risk than EPA would allow for carcinogens in food, for example.

RECOMMENDATIONS

- **EPA must immediately adopt a strict, health-protective standard for arsenic in tap water.** The Safe Drinking Water Act (SDWA) Amendments of 1996 required EPA to propose a revised arsenic standard (to replace the old standard set in 1942) by January 1, 2000, a deadline the agency has missed. This is the third time EPA has violated a statutory mandate to update the arsenic standard. EPA is required to finalize a new standard by January 1, 2001. We conclude -- as did NAS -- that EPA should expeditiously issue a stricter Maximum Contaminant Level standard for arsenic. EPA must consider that many Americans also have unavoidable exposure to arsenic in their food, so relatively low levels of arsenic in tap water can cause safety levels to be exceeded. A health-protective tap water arsenic standard should allow a maximum lifetime cancer risk no greater than that EPA has traditionally accepted (a level presenting a lifetime cancer risk from 1 in 1,000,000 to at most 1 in 10,000 for vulnerable or highly exposed individuals).

  This would require EPA to set a drinking water standard well below the current 50 ppb standard -- in the range of 1 ppb. Limitations in the analytical techniques widely used for measuring arsenic in water, however, would likely necessitate a standard of 3 ppb, rather than a standard of 1 ppb, because reliably quantifying arsenic at levels below this would be difficult using current standard lab equipment and practices.

said probably overestimate costs, indicate that the cost per household of a 2 ppb standard would be from $5 to $14 per month for the vast majority (87 percent) of affected consumers; users of small systems may have to pay significantly more. EPA's (admittedly high) estimates also project that nationally an arsenic standard of 2 ppb would cost $2.1 billion per year, and a 5 ppb standard would cost $686 million per year.

- **EPA should reduce its cross-media guidance level for arsenic and should fund improved analytical methods to lower detection limits for arsenic.** Health data indicate that EPA's current guidance level establishing the maximum recommended daily arsenic exposure, called a reference dose (which is unenforceable itself, but is used by EPA in developing enforceable standards in all environmental media, including water), is too high and may not protect vulnerable populations, such as children. To protect children, EPA should reduce this reference dose from 0.3 micrograms per kilogram per day (µg-kg per day) to at most 0.1 µg-kg per day, and should immediately reevaluate the reference dose in light of the 1999 NAS risk estimates, suggesting that the cancer risk at this level would still be unacceptable. In addition, EPA should fund efforts to reduce the level at which arsenic can be reliably detected in drinking water, so that it can be found down to levels at which it may pose a health risk (below 1 ppb).

- **Water systems should be honest with their customers about arsenic contamination and potential health risks.** Only if water systems tell their customers the truth about arsenic contamination in their tap water, and about the health threat it poses, will the public support efforts (including possible rate increases) to remedy the problem.

- **Systems with arsenic problems should work with government officials to clean up their source water.** Some systems may be able to reduce arsenic levels by cleaning up or changing the source of their water. For example, some arsenic contamination results from leaching of arsenic from old waste dumps, mines, or tailings, or from past use of arsenic-containing pesticides. Government officials and water systems should team up with citizens to remedy contamination at these sites so water supplies are not arsenic-contaminated. In addition, recent studies have shown that high groundwater pumping rates have increased arsenic levels in some wells. It should be investigated whether reducing pumping rates or reworking wells can reduce some systems' arsenic levels.

- **Water systems unable to get cleaner source water should treat to remove arsenic; state and federal funds should be increased to assist smaller Systems in paying for upgrades.** As noted above, there is readily available treatment technology that can remove arsenic from tap water, at a cost of about $5 to $14 per month per household for the vast majority of people (87 percent) served by systems with arsenic problems. Very small systems serving a small fraction of the population drinking arsenic-contaminated water, however, will often be more expensive to clean up per household (due to the lack of economies of scale). For these systems, federal and state assistance to improve treatment is available, and arsenic contamination should be a high priority for these drinking water funds. Additional federal and state funding through State Revolving Fund (SRF), USDA's Rural Utility Service, and other programs may also be needed. The SRF established by the SDWA Amendments of 1996 should be funded at least to the full authorized amount ($1 billion per year) to help smaller systems with arsenic problems.

- **EPA should improve its arsenic and other drinking water databases.** EPA should upgrade its drinking water database, known as the Safe Drinking Water Information System (SDWIS) so that it includes all of these arsenic data, as well as unregulated contaminant data, as required by the Safe Drinking Water Act -- and makes them accessible to the public. The SDWIS database must also be upgraded to include more accurate latitude and longitude ("lat-long") data. The ready availability and low cost of new GPS (global positioning system) units for recording lat-long coordinates -- available for a few hundred dollars -- should drive EPA to require accurate lat-long data for the distribution systems, treatment plants, and intakes of each public water system. Such data will have a wealth of uses for water systems, state and local officials, EPA, and the public in using GIS systems for protecting source water, for developing targeted and well-documented rules, and for other purposes.

Notes

1. The phrase "unacceptable cancer risk" is used here to mean water containing arsenic at a level posing a lifetime risk of dying from cancers in all internal organs -- bladder, kidney, liver, and lung -- of over 1 in 10,000, based on the methodologies, estimates, and cancer risk characterizations described in the National Academy of Sciences' recent report, *Arsenic in Drinking Water*, at 8, 301 (1999), and based on the standard assumption that a person consumes two liters of water per day. A 1 in 10,000 cancer risk traditionally is the highest cancer risk EPA ever allows in tap water when setting standards, although the agency usually seeks to set standards at a stricter level, posing a lower cancer risk. See Chapters 1 and 2 for details.

2. As discussed in Chapter 1, the 56 million population exposed figure is our best estimate of the average arsenic exposure levels of consumers in the 25 states included in the new EPA database analyzed in this report. While this analysis is conservative (it may underestimate the extent of exposure), an even more conservative analysis would suggest that a minimum of 34 million people in these 25 states drank water posing a significant cancer risk. The latter highly conservative low average estimate assumes, when calculating average arsenic levels, that no arsenic was in the water at times when early crude tests with a high reporting limit of, for example, 10 ppb, found none, even though subsequent more sensitive tests found arsenic. On the other hand, the mid-average approach assumes that arsenic

Attachment 20

EPA aims to cut levels of arsenic in well water

[1 3 Edition]

The San Diego Union - Tribune - San Diego, Calif.
Author: Steve LaRue
Date: Jun 5, 2000
Start Page: B.1
Section: LOCAL
Text Word Count: 1549

Document Text

For text of mac-produced charts, see microfilm.

Residents of several outlying areas in San Diego County and across the nation may be paying an unseen price for their rural lifestyles - - increased cancer risk -- health experts say.

The cause: the classic poison arsenic, a metal present in deep rocks, particularly in desert and mining areas. Underground water in these areas dissolves the poison and delivers low levels of it into humans who drink it.

The federal Environmental Protection Agency is proposing to shrink the limit on arsenic in drinking water to one-tenth the current limit, to five parts per billion from 50.

That would mean more stringent water testing requirements at a dozen water systems in this region that rely at least partly on well water and serve communities such as Borrego Springs, Camp Pendleton, Escondido, Jacumba, Poway, La Mesa and El Cajon.

Larger systems, such as the La Mesa-based Helix Water District, already have treatment plants that remove this and other contaminants. If arsenic levels are found to exceed the new health standard in smaller water districts, the cost to users to build treatment works could be considerable because it would be spread among relatively few customers.

The EPA says the proposed health standard could lower cancer risks for 22.5 million Americans, but could require customers of 2,000 to 2,500 small water districts in California, mostly in Southern California, to endure higher water rates to finance new treatment systems.

Nationwide, customers of 6,000 to 7,000 small water systems could face higher costs, the EPA says.

"A lot of systems that use wells are going to have to look more closely for arsenic than they have before," said Bruce Macler, chief drinking water toxicologist for the EPA's western regional office in San Francisco.

"I wouldn't be surprised if 30 to 40 percent of these systems have to do something," he said. "I am sure some of the systems in San Diego County will be impacted."

One part per billion, or ppb, is equivalent to about one drop of water in a large high school swimming pool, or one second in about 32 years.

The EPA's move to tighten the arsenic standard follows a 1999 study by the National Research Council. The existing standard is based on a level set in the early 1940s before arsenic was known to cause cancer. The EPA says it could pose long-term cancer risks in some areas of greater than one case of cancer per 100 people who drink water containing the maximum arsenic levels.

That is, one of every 100 people who drink water with 50 ppb of arsenic would be expected to develop one type of cancer during his or her life.

This is a much higher risk level than the one-per-million the EPA tolerates as a maximum for other drinking water contaminants.

The report concludes: "The current (standard) for arsenic in drinking water does not achieve the EPA's goals for public health protection and, therefore, requires downward revision as promptly as possible."

Water industry trade groups say a less strict standard, such as 10 parts per billion, might be more appropriate, and also a lot less expensive.

"We definitely agree that the standard has to come down, but we are a little apprehensive about what the number should be," said Krista Clark, regulatory specialist for the 442-member Association of California Water Agencies.

Costs could reach $100 per household per year in rural areas, she said, and should not be imposed until there is more scientific consensus on what the standard should be.

These charges, she warned, would reflect the high costs of building and maintaining water treatment works in rural areas where there are not many water customers to share those costs.

Meanwhile, a key environmental group is urging the EPA to make the new arsenic standard even more strict.

"We have called on the EPA to adopt a standard no higher than 3 ppb," said Erik Olson, senior attorney for the Natural Resources Defense Council, or NRDC.

"Clearly, it would be a substantial improvement to go from 50 ppb down to 5 ppb, but the total cancer risk at 5 ppb is still one in 1,000, which is far higher than EPA ever accepts (from other contaminants) in drinking water," he said.

Drinking arsenic-laced ground water over decades has been observed in other countries to increase the incidence of cancers that attack a variety of organs, from the bladder to the lungs, and to contribute to heart illness, federal officials say.

Studies of parts of India where arsenic levels approach 500 ppb indicate that 10 percent of the people who drink the water for long periods develop cancer, said the EPA's Macler.

How many San Diego County residents, or other Americans, may be at risk? Without standardized tests and monitoring procedures, experts say this is difficult to determine. For example, some testing procedures register a "not detectable" reading when the arsenic level is lower than 10 ppb or 20 ppb, experts say.

The vast majority of Southern California's 17 million water consumers, including most urban and suburban dwellers in San Diego County, will not be affected because most of their water comes from mountain snowpacks and rainfall captured as it flows down distant rivers.

Even when some of the wells in these large "surface water" systems contain high arsenic levels, their water is vastly diluted, then treated to remove this and other contaminants.

"The highest arsenic value we have seen in the last year is slightly over 2 ppb, so we are slightly over half of the proposed limit," said John Chaffin, the city of San Diego's water quality superintendent.

The city does draw water from a single well, in El Cajon, where arsenic levels were recorded at 10.2 ppb in 1994. But the water is treated to remove the arsenic and then greatly diluted before it is delivered to customers, Chaffin said.

The existing arsenic standard applies to so-called community water systems and larger systems. A community system is one with at least 15 service connections that supplies at least 25 people throughout the year.

The EPA is proposing to extend the new arsenic standard to include systems that regularly serve 25 or more people at least six months out of the year.

These could be small water companies or special water districts. Neither the existing nor the proposed arsenic standard would apply to so-called "transient" systems, which people do not use continually, such as wells supplying water for rural restaurants or gas stations. Private wells supplying farms and rural homes would not fall under the standard, either.

Private well owners can have their water tested for arsenic and can remove it by using filters containing iron oxide or aluminum oxide.

The San Diego County Department of Health Services monitors arsenic testing at community water systems but refused to disclose which of them has tested above 5 ppb for arsenic. A spokesman said the reason is that the

proposed standard has not been approved, and specific testing procedures have not been identified by the State Department of Health Services.

"We are expecting some kind of guidance from the state as to how to implement the new standard," but there is little doubt that several systems in San Diego County will exceed it, said Frank Gabrian, supervising environmental health specialist.

Counties submit well test results to the states, and states report them to the federal government. Some of these results were obtained under the Freedom of Information Act by the NRDC and posted on the group's Web site (http://www.nrdc.org).

But the results may not tell the whole story.

They suggest, for example, that 1,200 or more residents of Borrego Springs consumed well water in 1997 that contained an average level of 5.6 ppb of arsenic, and that well arsenic concentrations there reached a peak of 10.2 ppb in 1988.

But Linden Burzell, chief engineer for the Borrego Water District, said he is not familiar with such test results.

"We measured the wells in 1998 and have taken hundreds of different samples, and we will be doing this again next year," Burzell said. "All of our 12 wells show that arsenic is undetectable except for one well, where it is at 2 ppb, so arsenic levels in the Borrego Valley aquifer are very low."

The NRDC data also indicate arsenic levels that might exceed the new standard in wells in Jacumba and at Camp Pendleton.

State and county officials said new compliance and testing rules will be needed to tell which water districts comply with the new arsenic standard. The state would be expected to issue these rules about 18 months after a new federal standard is approved.

Credit: STAFF WRITER

Abstract (Document Summary)

The EPA's move to tighten the arsenic standard follows a 1999 study by the National Research Council. The existing standard is based on a level set in the early 1940s before arsenic was known to cause cancer. The EPA says it could pose long-term cancer risks in some areas of greater than one case of cancer per 100 people who drink water containing the maximum arsenic levels.

They suggest, for example, that 1,200 or more residents of Borrego Springs consumed well water in 1997 that contained an average level of 5.6 ppb of arsenic, and that well arsenic concentrations there reached a peak of 10.2 ppb in 1988.

1 PIC | 3 CHARTS | 1 DIAGRAM; Caption: 1. Marc Hall, a San Diego Water Department chemist, diluted a sample from Otay Lakes. The EPA has proposed lowering the limit on arsenic in drinking water. 2,3,4,5. Arsenic in drinking water (B-3) 2. The element arsenic occurs naturally in the soil. In many areas, it dissolves into the public water supply. (B-3) 3,4. Long-term exposure hazards (B-3) 5. Web sites for more information (B-3); Credit: 1. Earnie Grafton/ Union-Tribune 2,3,4,5. SOURCES: U.S. Environmental Protection Agency; California Department for Health Services; Natural Resources Defense Fund; Knight Ridder/Tribune | UNION-TRIBUNE

Attachment 21

PRESS RELEASE

Confidential Papers Show Exxon Hand in White House Move to Oust Top Scientist from International Global Warming Panel

April 03, 2002

MEDIA CONTACTS

Jon Coifman, 202-289-2404 or Elizabeth Heyd 202-289-2424

Oil Company Memo Calls for Dr. Watson's Dismissal; Administration Obliges

WASHINGTON (April 3, 2002) -- The Bush administration this week moved to oust a top scientific official targeted by ExxonMobil in a confidential memo to the White House. Bold language in the ExxonMobil papers released today by NRDC (the Natural Resources Defense Council) reflects a brazen, behind-the-scenes effort by the oil company and other energy giants to disrupt the principal international science assessment program on global warming.

Dr. Robert Watson, a highly respected atmospheric scientist, has been chair of the Intergovernmental Panel on Climate Change (IPCC) since 1996. Operating under United Nations auspices, the 2500-member expert panel provides policymakers around the world with rigorous, consensus-based assessments generally regarded as the most authoritative word on global warming and its causes.

Without formal announcement, the administration has decided to oppose Watson's appointment to a second term as IPCC chair, seriously damaging his prospects when representatives of more than 100 governments meet in Geneva April 17-20 to elect a new IPCC head.

The memorandum, obtained by NRDC from the White House Council on Environmental Quality under the Freedom of Information Act, shows that ExxonMobil began a secret campaign for Dr. Watson's removal in the first weeks of the Bush administration, and reveals ExxonMobil's intention to replace Watson and other key scientists with contrarians known for disagreeing with the prevailing consensus that man-made pollution is causing global warming.

In meetings this week with State Department officials, lobbyists for the coal industry, electric utilities, and automakers joined ExxonMobil's call to replace Watson.

"It's bad enough that ExxonMobil controls White House energy and climate policies," said Daniel Lashof, science director of the NRDC Climate Center. "Now they want to control the science too."

Under Watson's tenure, the IPCC last year produced its third comprehensive assessment of the state of climate science, concluding that "[t]here is new and stronger evidence that most of the warming observed over the last 50 years is attributable to human activities," and predicting that average global temperatures will rise between 3 and 10 degrees Fahrenheit by the end of the century -- conclusions reaffirmed last spring at White House request by the National Academy of Sciences.

In a letter yesterday to Undersecretary of State Paula Dobriansky, NRDC's Lashof said: "The industry effort to block the reappointment of Dr. Watson is a thinly veiled attempt to undermine the effectiveness of the IPCC as a body that produces high quality, objective scientific assessments. I urge you to reject this campaign and to give Dr. Watson the United States' strongest possible support."

The Natural Resources Defense Council is a national, non-profit organization of scientists, lawyers and environmental specialists dedicated to protecting public health and the environment. Founded in 1970, NRDC has more than 500,000 members nationwide, served from offices in New York, Washington, Los Angeles and San Francisco.

Additional Downloadable Materials for the Press

ExxonMobil Memorandum in PDF format, 232k.

NRDC letter to State Department in Microsoft Word format, 22k.

Facsimile Cover Sheet

TO: **John Howard**
Office: CEQ
FAX: **202.456.2710**
Telephone: 202.456.6540

FROM: **Randy Randol**
Company: ExxonMobil - Washington Office
FAX: **202.862.0267** (Backup: 202.862.0268)
Telephone: 202.862.0220 (Backup:202.862.0223)
E-Mail: arthur.g.randol@exxon.com

A. G. (Randy) Randol III, Ph.D.
Senior Environmental Advisor

ExxonMobil

Exxon Mobil Corporation
2001 Pennsylvania Avenue, N.W.
Suite 300
Washington, District of Columbia 20006-1813
202 862 0220 Telephone
202 862 0267 Facsimile
arthur.g.randol@exxon.com

Date/Time: 6 Feb 2001, 10:00 a.m.

Pages including Cover: 18

Regarding: *Bush Team for IPCC Negotiations*

Attached is a brief memo outlining the issues related to the on-going IPCC negotiations on the Third Assessment Report. I have also attached other material that may be useful to you.

I will call to discuss the recommendations regarding the team that can better represent the Bush Administration interests until key appointments and re-assessments are made.

Randy

Global Climate Science-Issues for 2001

A. Intergovernmental Panel on Climate Change (IPCC)

1. The IPCC is on schedule to issue in late September 2001 its Third Assessment Report (TAR), composed of three Working Group Reports on the science, impacts and mitigation of climate change and a Synthesis Report. The IPCC is headed by Robert Watson, an American who is also the chief science person at the World Bank (Director, Environment Dept.) Watson was hand picked by Al Gore and served in the Clinton/Gore White House Office of Science and Technology policy. His tenure at the IPCC ends with the completion of the TAR. However, he could be extended at an IPCC session this year or next.

During the Hague meeting in November, Watson presented a sneak preview of the Third Assessment Report with the following caveat " *None of the conclusions presented in this report are taken from the TAR, but are consistent with the draft conclusions, which are subject to change until final government approval and acceptance early next year.*" His statement belied his real intent, which was to get media coverage of his views before there was a chance for the process to challenge his personal agenda.

Issue: Can Watson be replaced now at the request of the U.S.?

The Working Group Reports are prepared by scientists, economists, engineers, and others, including some persons from industry and environmental organizations. **Each report includes a "Summary for Policy Makers" (SPM) that is approved by IPCC governments by consensus in a line-by-line review at a Working Group session** with the underlying report (approx. 1000 pages) accepted by the Group at that session.

In the case of the Working Group I report on science, the Group met in plenary in Shanghai, China on January 17-20, approved the SPM, and accepted the report. The US delegation (Moitke lead) was satisfied to raise no objections on the tone and content of the report. To avoid accountability to the Bush Administration, the meeting actually ran until 1:00 a.m. on January 21 which was exactly January 20, 12:00 noon in the U.S. The U.S. was represented by Clinton/Gore carry-overs with aggressive agendas:

1. State Department: **Jeff Moitke**, Deputy Director, Global Change Office, Oceans and International Environmental and Scientific Affairs (and Deputy Chief of Mission, Lesotho)

2. White House Office of Science and Technology Policy: **Rosina Bierbaum**, Associate Director, Environment,

3. White House U.S. Global Change Research Program: **Michael MacCracken**, Executive Director, National Assessment Coordination Office.

Global Climate Science-Issues for 2001

Bierbaum and MacCracken were both actively involved in the production of the US National Assessment that has been roundly criticized for its political and scientific bias. The National Assessment was driven by a political schedule to help the Gore campaign. Several controlled leaks were used to get maximum media attention since Congressional oversight forced a delay in the release of the report.

Issue: Have Bierbaum and MacCracken been removed from their positions of influence?

Issue: What was the U.S. position on the WG1 Report? Did it reflect the comments received?

While the SPM was written to highlight the "human fingerprint", it also states that: "Further research is required to improve the ability to detect, attribute and understand climate change, to reduce uncertainties, and to project future climate changes."

According to an AP story, Watson, in commenting on the report, which was released by the Group, but which has not yet been accepted by the full IPCC, said:

> "The United States is way off meeting its targets," said Watson. "A country like China has done more, in my opinion, than a country like the United States to move forward in economic development while remaining environmentally sensitive."

China, of course, has no commitments under the Kyoto Protocol and its greenhouse gas emissions are growing and will soon exceed those of the U.S.

2. **Working Group II is scheduled to meet on the "Impacts of Climate Change" in plenary in Geneva, Switzerland, from February 12-16.** Reportedly, the U.S. has submitted comments on the draft report by January 8, which was the deadline. Those comments have not been made public.

Issue: Who has reviewed those comments?

Issue: What is the U.S. position on the report?

Issue: Who will represent the U.S. at this meeting?

3. Working Group III is scheduled to meet on "Mitigation of Climate Change" in plenary in **Accra, Ghana, from February 28 to March 3.** Government comments on that draft report/SPM are due to be submitted by January 29.

Issue: Who has reviewed those comments?

Issue: What is the U.S. position on the report?

Issue: Who will represent the U.S.? What is U.S. position?

4. On **April 4-6, 2001**, the full IPCC is scheduled to meet in plenary in **Nairobi, Kenya**, to accept by consensus the results of the three Working Groups.

Issue: Will the U.S. revisit the Working Group I comments of the Clinton/Gore representatives?

Issue: Who will represent the U.S. and what will be the U.S. position?

Issue: Can this report be deferred until the US has provided updated input(30-45 days)?

5. **The last element of the TAR is the Synthesis Report (SR) that is still being drafted under Robert Watson's control.** A draft of the SR, including its SPM, is to be sent out for simultaneous expert and Government review and comment with a deadline of May 29. A second draft is scheduled to be given to Governments only for their review and comment on July 6 with a deadline of August 31. **The IPCC plenary will meet in London from September 24-29 to adopt/approve the Synthesis Report by consensus.**

Issue: Can this report be deferred at least 45 days?

Thereafter the entire TAR will be released(in time for political use at COP-7).

COP-6, held in The Hague last November, ended without finishing its work on implementation of the Kyoto Protocol and with an understanding that it would meet again in 2001, but with no date established. The SBI and SBSTA are scheduled to meet in Bonn, Germany, from May 21-June 1. Some Parties want COP-6 to reconvene during that time. **COP-7 is scheduled to meet October 29-November 9 in Marrakech, Morocco, together with the subsidiary bodies.**

Global Climate Science-Issues for 2001

Recommendations:

1. Restructure the U.S. attendance at upcoming IPCC meetings to assure none of the Clinton/Gore proponents are involved in any decisional activities.

a. Appoint **Dr. John Christy**, University of Alabama-Huntsville(Lead Author-Working Group I) as science lead for the balance of the IPCC process. Phone: 256.961.7763 This replaces Bierbaum and MacCracken.

b. Appoint **Dr. Richard Lindzen**, MIT,(Lead Author-Working Group I) as a co-lead to conduct an immediate review of the comments on the Working Group reports(I, II and III) and to review the US comments to be submitted(II, III). Phone: 617.253.2432

c. Detail **Dr. Joe Friday**, National Research Council-Board on Atmospheric Sciences and Climate(Coordinated the "Research Pathways for the Next Decade" report that the Clinton Admin tried to bury), to work with Christy/Lindzen. Phone: 202.334.3512

d. Detail someone from the State Dept to work under the direction of Christy/Lindzen for the "consenstus negotiations". This replaces Moitke.

2. Request that the April 4-6 full IPCC meeting be deferred at least 30 days until a re-assessment of US input can be made.

3. Request that all action related to the Third Assessment Report is deferred until the IPCC process is complete (30-45 days). This must include the Watson release of the draft Synthesis Report.

4. Explore the possibility of asking Speaker Hastert to make Dr. Harlan Watson, Hse Science Committee, available to work with the team. Dr. Watson has been recommended for the Assistant Secretary of State for Oceans position.

Attachment 22

The Nation

Charges Fly Over Science Panel Pick

April 04, 2002 | ELIZABETH SHOGREN | TIMES STAFF WRITER

WASHINGTON — The Bush administration is pushing for an engineer from India to take over the helm of an influential international science panel on global warming that is now headed by an American atmospheric chemist who has been criticized by the energy industry.

Energy lobbyists have accused Robert T. Watson, chairman of the Intergovernmental Panel on Climate Change, of promoting his own agenda. In a memo to the White House a year ago, a senior Exxon Mobil Corp. official urged the administration to push him out.

"Can Watson be replaced now at the request of the U.S.?" asks the memo, which was obtained from the White House through a Freedom of Information Act request by the Natural Resources Defense Council, an environmental group.

The council accuses the Bush administration of turning its back on solid science and bending to industry wishes by supporting Watson's challenger, Dr. Rajendra K. Pachauri. In an election later this month, the 100-plus member countries of the climate panel will have one vote each on the chairmanship.

"It's bad enough that Exxon Mobil controls White House energy and climate policies," said Daniel Lashof, science director of the NRDC Climate Center. "Now they want to control the science too."

Also promoting Watson's reelection are leading climate scientists such as Ralph J. Cicerone, chancellor of UC Irvine and chairman of a National Academy of Sciences panel that reviewed global warming issues for the Bush White House.

Bush administration officials said they decided to support Pachauri because his background as an engineer and an economist prepares him to determine the global implications of climate science. They said the administration also believes that a chairman from the developing world would signal that global climate change is a problem for the whole world, not just for wealthy nations.

Environmentalists and Watson say the administration's decision reflects its discomfort with having Watson on a prestigious platform for broadcasting to the world the seriousness of global climate change resulting from the burning of coal, gas, oil and other fossil fuels.

"There is new and stronger evidence that most of the warming observed over the last 50 years is attributable to human activities," the climate change panel concluded last year in its third comprehensive assessment under Watson's chairmanship.

"I've been hearing over the last month or two that a small vocal part of the energy industry has been putting a lot of pressure on the U.S. government not to reelect me," said Watson, who was the associate director for environment in the White House Office of Science and Technology during President Clinton's first term.

Watson said he believes he still has a good chance to win reelection. Officials from many countries have told him they will support his candidacy because of his ability to organize thousands of scientists to review documents and develop coherent analyses of the complicated problem.

Watson said he hopes the Bush administration does not believe energy lobbyists' claims that he advocates tough government regulations of industries that emit carbon dioxide, the major greenhouse gas produced from human activity.

"My advocacy is for truth in science--that we do get the very best scientists from around the world," Watson said. "The argument that I'm an advocate for regulations against the oil industry is incorrect."

President Bush's climate change policy calls on industry to voluntarily reduce carbon dioxide emissions.

White House spokesman Scott McClellan disputed the claim that the Exxon Mobil memo influenced the White House decision on the IPCC chairmanship. The memo "was faxed to an individual who had no involvement with IPCC leadership issues and took no action on the memo," he said.

Neither he nor any official provided by the Bush administration to comment on the issue flatly denied that industry influence played a role in the State Department's decision to side with Pachauri.

Energy industry lobbyists met Tuesday with State Department officials before the decision to support Pachauri was announced. But a Bush administration official said the decision already had been made.

Attachment 23

Bulletin of the Atomic Scientists

ISSN: 0096-3402 (Print) 1938-3282 (Online) Journal homepage: http://www.tandfonline.com/loi/rbul20

The protection paradox

Hans M. Kristensen, Matthew G. McKinzie & Robert S. Norris

To cite this article: Hans M. Kristensen, Matthew G. McKinzie & Robert S. Norris (2004) The protection paradox, Bulletin of the Atomic Scientists, 60:2, 68-77, DOI: 10.1080/00963402.2004.11460771

To link to this article: http://dx.doi.org/10.1080/00963402.2004.11460771

Published online: 15 Sep 2015.

The protection paradox

by Hans M. Kristensen, Matthew G. McKinzie & Robert S. Norris

Who's kidding who? If you think a missile defense deployment will make the world safer, take a look at how the United States reacted to the Soviet missile defense of Moscow.

THE UNITED STATES PLANS TO begin deployment of a limited ballistic missile defense system at Fort Greely in Alaska and Vandenberg Air Force Base in California by the end of 2004. With 10 silo-based interceptors intended to shoot down long-range ballistic missiles, the system will serve as "a starting point for fielding improved and expanded missile defense capabilities later," according to the White House. The system is expected to grow to 20 silo-based interceptors in 2005, and up to 100 interceptors in the following years.

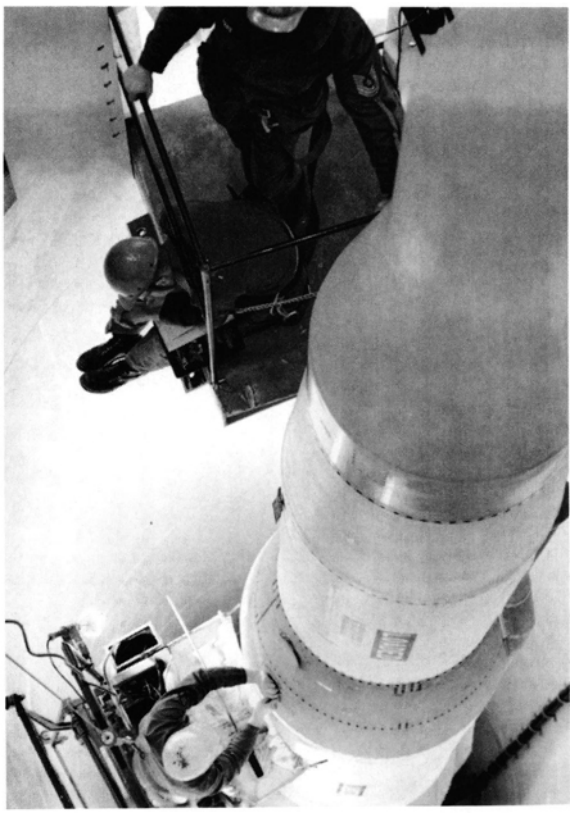
How will other nuclear powers respond? Some suggest that Russia might modernize its forces to be able to overwhelm the U.S. system and that China might improve its intercontinental ballistic missiles (ICBMs) to ensure the credibility of its deterrent. But the Bush administration insists this won't happen.

"Our missile defenses will be no threat to Russia," Douglas J. Feith, undersecretary of defense for policy, told the Senate Foreign Relations Committee in July 2001. Such U.S. defenses will not affect Russian capabilities, he said, so "there is no incentive for Russia to spend scarce resources to try to overcome them." And China, Feith claimed, "will continue [its] modernization whether or not we build missile defenses."

How can the Bush administration be so sure of how Russia or China will react? Its position is more wishful thinking than careful analysis. Had it bothered to examine how the United States itself reacted when faced with a Soviet missile defense system, it might have come to a different conclusion.

Documents recently declassified under the Freedom of Information Act (FOIA) reveal that in 1968 U.S. war planners sought to overwhelm Soviet defenses with enough nuclear firepower to kill tens of millions of people. The documents reveal that the United States considered all components of the Soviet anti-ballistic missile (ABM) system—missile interceptors, battle radars, and distant early warning radars—as high-priority targets for nuclear weapons.

Hans M. Kristensen, Matthew G. McKinzie, and Robert S. Norris work for the Natural Resources Defense Council in Washington, D.C. A footnoted version of this article appears online at www.thebulletin.org.



Missiles like this Minuteman II, shown in its North Dakota launcher, could have targeted Russian complexes.

The emergence of a Soviet missile defense system also spurred U.S. development of penetration aids ("pen-aids") and multiple independently targetable reentry vehicles (MIRVs), which vastly increased the U.S. stockpile. The United States undertook these efforts even though the Soviet ABM system was limited—similar in scale to the non-nuclear system planned by the Bush administration, which purports to defend against small attacks.

By reexamining the Soviet missile defense system of the late 1960s and how U.S. war planners might have planned to destroy it, and then by looking at how nuclear targeting is done today, it is clear that construction of a U.S. missile defense is actually cause for concern.

Soviet missile defense, 1968

The Soviet Union first deployed ballistic missile defense systems in the late 1960s. The most important was the A-35 anti-ballistic missile (ABM-1) defense system around Moscow, which began limited service in November 1967 with a few interceptors. The second, known as the Tallinn system, was located near Leningrad (now St. Petersburg) and became operational around the same time.

The A-35 Moscow system was originally designed to simultaneously intercept as many as eight incoming reentry vehicles. But there were doubts about whether it could intercept that many missiles, or missiles with multiple warheads and/or pen-aids (decoys that confuse radars). By 1968, the system was required to intercept only a single warhead or a single strike.

The initial system included 64 Galosh interceptors (ABM-1A, later upgraded to ABM-1B) located at four launch complexes outside Moscow. The Galosh had a 300-kilometer range and carried a warhead with a 2–3 megaton yield. Descriptions of the Soviet ABM system normally mention only four complexes, but a 1970 CIA report reveals that each complex consisted of two distinct launch sites separated by 4–7 kilometers. The four pairs of launch sites, the last of which became operational in early 1970, were arranged in a half-circle facing northwest, 85 miles (136 kilometers) from Moscow's center. Each launch site had eight reloadable aboveground launchers and three Try Add radars—one large radar for tracking and two smaller ones for tracking and guidance. A large Dog House tracking radar was built about 68 miles (109 kilometers) southwest of Moscow to track incoming reentry vehicles and provide battle management.

In addition to revealing the interceptor launch complexes, a CIA map released under FOIA shows that Moscow was also surrounded by 48 launch sites equipped with SA-1 Guild surface-to-air missiles. Twenty-six of the sites circled Moscow about 50 miles (80 kilometers) from its center; the other 22 sites formed an inner ring about 30 miles (48 kilometers) from Moscow's center. The 12-meter-long Guild missile had a range of 50 kilometers and could carry either a conventional or nuclear warhead.

Successful interception of reentry vehicles requires advance warning. In 1964, construction began on Hen House early warning radars, one at Skrunda in Lithuania and another at Olenegorsk on the Kola Peninsula. Hen House radars were designed to assess the size of an attack, confirm warnings from satellites and over-the-horizon radars, and provide target-tracking data to support ABM interceptor launches. The radars, located in the corridors through which U.S. ICBMs would strike Moscow, were almost entirely undefended and extremely vulnerable to the blackout that would result from nuclear airbursts.

The Tallinn system, named for the location where it was first detected, was deployed in a barrier line across the northwestern parts of European Russia, around Leningrad, and some parts of the southern approaches. After the conventionally armed SA-5 Griffon system was terminated in 1963, deployment of nuclear-capable SA-5B Gammon interceptors began at the old sites, with new sites constructed at Cherepovets, Liepaja, and Tallinn. The upgraded system became operational around 1966 or 1967.

In 1968, the total Tallinn system consisted of nearly 30 operational launch complexes with a similar number under construction. Each complex generally consisted of three launch sites. Each site had six SA-5B Gammon launchers and a

USAF

modest-sized Square Pair radar. Of the 30 operational complexes, only six were close enough to the Hen House radars in Olenegorsk and Skrunda to have a potential ABM role (see "Soviet ABM System, 1968," p. 73).

There was considerable disagreement within the U.S. intelligence community at the time about whether the improved Tallinn system was to defend against aircraft, ballistic missiles, or some combination of the two. The Defense Intelligence Agency (DIA) agreed with the air force, which in late 1967 concluded that the system "possesses significant capabilities in both a terminal defense and area ABM role." But six months later, in a memorandum for President Lyndon Johnson, newly appointed Defense Secretary Clark Clifford said an ABM capability "now appears unlikely."

The CIA concluded that it did "not believe there is any deployment of ABM defenses outside the Moscow area," and the Tallinn system was "unlikely to have a present ABM capability," though it acknowledged, "the state of available evidence does not permit us to exclude this possibility." This view was shared by the navy, which decided that the system had "negligible capabilities against ballistic missiles."

There was general agreement that the limited Moscow and Tallinn systems would not be able to counter a large U.S. ballistic missile attack. In fact, the CIA later concluded that it "doubt[ed] that the Soviets will have an ABM system worth deploying against the U.S. threat in the foreseeable future."

The effect on U.S. nuclear planning

Despite disagreements and doubts, U.S. nuclear planners gave high priority to targeting the Moscow and Tallinn systems, worrying that even a limited ABM capability could diminish a strike against Soviet ICBM silos by U.S. ICBMs, which would overfly Moscow.

Soviet planners estimated in the early 1970s that Moscow would be targeted by at least 60 warheads of 1 megaton each. Newly declassified U.S. documents show that they were fairly accurate. A strike plan against the Moscow and Tallinn defenses, to ensure "penetration of the ICBM force," was incorporated into the single integrated operational plan (SIOP) war plan and entered into effect January 1, 1968. In addition to an undisclosed number of Polaris submarine-launched ballistic missiles (SLBMs), the plan involved "more than 100 Minuteman" ICBMs—about 10 percent of the U.S. ICBM force at the time. The attack would come in two closely coordinated waves. In the first salvo, Minuteman I/II and Polaris missiles would strike the Hen House early warning radars and their Tallinn system defenses. In the second wave, the Dog House radar and the Try Add system around Moscow would be attacked.

Assumptions about the 1968 attack

In attempting to reconstruct how U.S. nuclear war targeters might have devised such a strike plan we have made some assumptions about the targets and the weapons. The CIA's 1967 National Intelligence Estimate concluded that Moscow's ABM system did not "cover all of the multidirectional U.S. missile threats to Moscow; it is subject to saturation and exhaustion," and "none of the system components are hardened against nuclear bursts."

The strike plan would likely have exploited these weaknesses to the fullest and made use of the surprise effect of the significantly shorter flight time of SLBMs. So we have assumed that the Polaris missiles were targeted against the soft Hen House and Dog

Projected U.S. ABM suppression strike, 1968*

Target	Weapon**		Warhead		Total	
	Type	No.	Type	Yield (kt)	Warheads	Yield (kt)
Moscow system						
Dog House radar	Polaris A3	2	W58	200	6	1,200
Eight ABM launch complexes	Minuteman I/II	64	W56	1,000	64	64,000
Subtotal		*66*			*70*	*65,200*
Tallinn system						
Tallinn launch complex	Minuteman I/II	8	W56	1,000	8	8,000
Liepaja launch complex	Minuteman I/II	8	W56	1,000	8	8,000
Cherepovets launch complex	Minuteman I/II	8	W56	1,000	8	8,000
Three Leningrad complexes	Minuteman I/II	24	W56	1,000	24	24,000
Subtotal		*48*			*48*	*48,000*
Early warning radars***						
Hen House (Skrunda)	Polaris A3	2	W58	200	6	1,200
Hen House (Olenegorsk)	Polaris A3	2	W58	200	6	1,200
Subtotal		*4*			*12*	*2,400*
Total		**118**			**130**	**115,600**

kt=kilotons. *Based on 100+ Minuteman I/II missiles, plus Polaris missiles, designated for 1968 Soviet ABM suppression. (U.S. Strategic Air Command, "History of U.S. Strategic Air Command January–June 1968," February 1969, p. 300. Partially declassified and released under FOIA.) **The assignment of individual weapons to individual targets is not known. We assume each launch complex was targeted by eight Minuteman missiles, each carrying one W56 warhead (1-megaton yield). ***Two other Hen House radars were located near China but could not detect missiles launched over the North Pole.

Characteristics of U.S. nuclear weapons

	Weapon	Yield (kilotons)	Accuracy (meters)*	Reliability**	MIRVs
1968					
	W56 (Minuteman I/II)	1,200	930	80 percent	1
	W58 (Polaris A3)	200	1,480	80 percent	3
1989					
	W78 (Minuteman III)	335	300	80 percent	2–3
	W76 (Trident I C4)	100	460	80 percent	8

MIRVs=multiple independently targetable reentry vehicles. *Circular error probable. **Average reliability.

House radars, while Minuteman ICBMs were focused on the interceptor complexes. Moreover, since we don't know the capability the nuclear war planners assigned SA-5B and ABM-1B interceptors, or whether they considered these longer-range Moscow interceptors more capable (they probably were), we have assigned an equal number of attacking warheads per launch site.

Based on these assumptions and detailed calculations described below, the use of "more than 100 Minuteman" ICBMs and at least six Polaris SLBMs against the Soviet missile defense system's 17 individual facilities results in a staggering average of eight 1-megaton warheads per interceptor launch site around Moscow and Leningrad. The combined force of the strike exceeds 115 megatons—the equivalent of more than 7,500 Hiroshima bombs. Under these assumptions, the Moscow system would be clobbered with 70 warheads; the Tallinn system would be hit with 48 (see "Projected U.S. ABM Suppression Strike, 1968," p. 71).

Modeling the 1968 strike

To better understand the methodology by which U.S. nuclear war planners probably arrived at such an enormous strike plan, we performed calculations of target hardness, damage expectancies, and nuclear weapons effects. Our assumptions about the characteristics of the two types of attacking U.S. nuclear weapons are provided (see "Characteristics of U.S. Nuclear Weapons," above). It is important to note that at the time, high yields were used to compensate for the weapons' relative inaccuracy. A 1-megaton warhead can destroy residential structures out to a radius of about 4.5 kilometers from its ground zero. Many currently deployed U.S. nuclear weapons can do more damage at lower yields because of significantly higher accuracies.

This strike has two types of targets: ABM radars, and surface-launched ABM interceptor missiles. The targets' hardness and the characteristics of the attacking weapons would dictate to 1968's U.S. nuclear war planners how many nuclear weapons to assign each target, and, for each weapon, the height of burst (HOB).

The height of burst determines whether there is fallout from a nuclear explosion; above a certain height, no fallout would be expected because the detonation is too high to kick up ground debris. For the attacking weapons in this scenario, the "no-fallout HOB" is 935 meters for a 1.2-megaton weapon and 457 meters for a 200-kiloton weapon. To increase damage to a hardened target, war planners may call for a HOB lower than the no-fallout height. The "optimum HOB" maximizes the area exposed to a given blast pressure. For some targets and nuclear yields, the optimum HOB is above the no-fallout height (as at Hiroshima and Nagasaki, for example).

A high-yield nuclear weapon detonated at a lower height could produce hazardous radiation levels hundreds of miles from ground zero. With information from the partially declassified 1989 NATO Target Data Inventory (NTDI) Handbook, we calculated the hardness of the Soviet ABM targets and the optimum heights of burst for the attacking weapons. The optimum heights of burst are above the no-fallout HOB for both target types; this would avoid radiation contamination of Russia and Europe. Factoring in weapon accuracy and reliability, we can also compute the kill probability for an individual warhead on a specific target (see "Optimized U.S. Nuclear Forces Attack on Soviet ABM Targets," p. 74).

Our calculations show that, using this methodology, a couple of W56 Minuteman warheads were needed to destroy each ABM launch site. The fact that the U.S. nuclear war planners of 1968 assigned about eight warheads to each target implies that they were concerned with the effectiveness of the Soviet missile defenses and used extra warheads to overwhelm them. The six Polaris warheads assigned to each radar target would have achieved a combined 88 percent kill probability.

Substantial blast and fire damage would be expected from the strike. Central Moscow would be initially undamaged but surrounded by a semi-circle of fire soon after the attack. If rain or snow were falling, radioactive contamination of Moscow might occur because of the phenomenon of rainout.

Pen-aids and MIRVs

Our reconstruction of the ABM strike does not take into account how well the Soviet missile defense systems would have worked. What our calculations do show, however, is that U.S. planners added a large number of weapons to the strike plan to overcome any attrition by the system.

In the early to mid-1960s, in anticipation of the Soviet missile defense

system, the United States developed pen-aids (decoys and chaff) to confuse interceptors. The United States wanted all its missile systems, whether SLBMs or ICBMs, "to be equipped with decoys capable of penetrating both area and local ballistic missile defenses." Some U.S. ICBMs had pen-aids, others did not; the Polaris SLBMs did not carry decoys (although subsequent Poseidon and Trident weapon systems did). In the 1968 strike plan described above, the Minuteman I reentry vehicles were equipped with "retro-rockets," and the Minuteman II carried Mk-11C reentry vehicles and Mk-1 pen-aids when available.

Another fundamental U.S. countermeasure to "saturate" the Soviet ABM system was the development and deployment of MIRVs. Many declassified documents from the time describe the MIRV development effort in an ABM context. The Polaris A3 carried three reentry vehicles, but the Poseidon SLBM that began replacing it in 1971 carried an average of 10 MIRVed warheads. Each warhead had a yield of approximately 50 kilotons and more than three times the accuracy of the Polaris A3. This meant the Poseidon could "be used to saturate an ABM defense or to attack independent soft targets."

The Minuteman III, deployed in 1970, and the current Peacekeeper ICBM carry two or three and 10 MIRVs, respectively. Individual missiles were eventually configured with different mixes of reentry vehicles and pen-aids to meet specific requirements of the mission.

British nuclear targeting of ABM systems

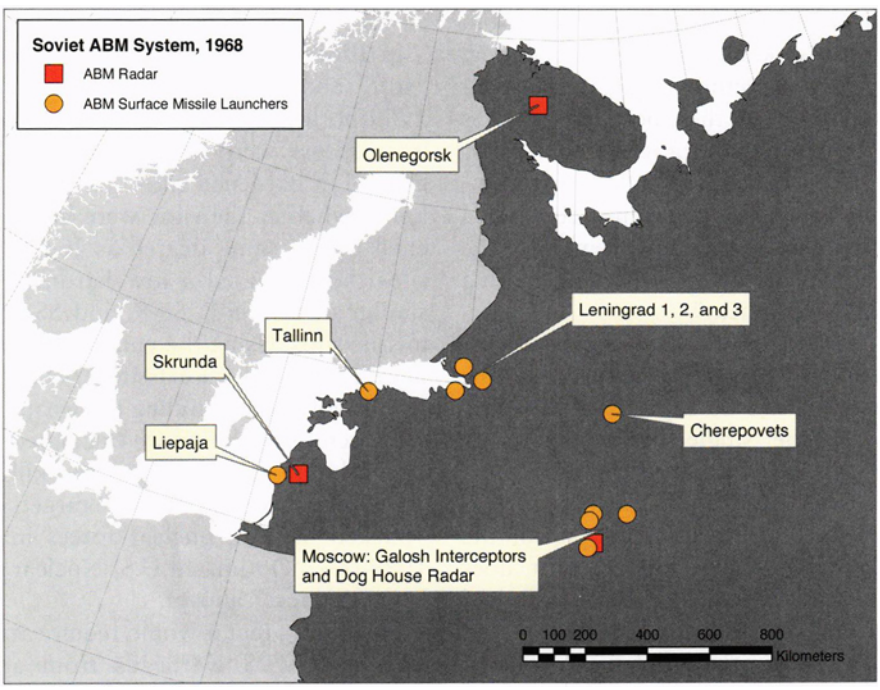
A British war plan supplemented the U.S. one. The first British nuclear-powered ballistic missile submarine (SSBN), the *Resolution*, sailed its first patrol in June 1968 armed with 16 U.S.-supplied Polaris missiles, each carrying three 200-kiloton warheads. Three more subs followed in June 1969, August 1969, and September 1970. The Polaris force took over the strategic role of the V-bomber.

By the end of the 1960s, targeting may have focused on Moscow, with all the missiles of a nuclear submarine committed to destroying the ABM system and the city. The capability of the Moscow ABM system might have limited the flexibility of British targeting by tying down most of the deployed force. Polaris appears to have been judged much more effective against the SA-5B Gammon interceptors of the Tallinn system. A 1970 study published by the British Atomic Energy Authority concluded that SA-5B interceptors were not a threat to British Polaris missiles, and that it would take only two Polaris missile payloads to saturate a standard SA-5B battery.

In 1972, the British government decided to develop a new front end for the Polaris missiles "designed specifically to penetrate [the] anti-ballistic missile defenses" around Moscow. This improved system, called Chevaline, was deployed in 1982. It carried pen-aids and three 40-kiloton maneuverable reentry vehicles that were "hardened" against the radiation effects of the nuclear ABM interceptors.

The Chevaline tied British targeting to Moscow. That changed in 1998, when Britain deployed Trident D5 missiles on four Vanguard-class SSBNs, returning flexibility to the war planners. "It is more than just the destruction of Moscow," said Field Marshall Nigel Bagnall, British chief of general staff from 1985 to 1988, "it is the destruction of the command and control system."

From late 1970 (when the British SSBN force became operational) through 1996 (when the Chevaline's operational deployment ended), the combined number of U.S. and British weapons assigned to suppress the Soviet ABM system may have been well over 200 warheads.



The Soviet ABM upgrade

Aware of the severe limitations of its A-35 Moscow ABM system, the Soviet Union began upgrading it in the mid-1970s. Like its predecessor, the upgraded system, called A-135, was designed merely to provide an "adequate" defense (as opposed to an "optimum" defense) against threats like a renegade U.S. SLBM attack, a "limited, provocative" U.S. ICBM at-

Optimized U.S. nuclear forces attack on Soviet ABM targets*

Attacking warhead	Target type	Optimum HOB**	Kill probability (excluding reliability)	Kill probability (including reliability)
1968				
W56; 1,200 kilotons	SA-5B/ABM-1B surface-to-air missiles	2,000 m	99 percent	79 percent
W58; 200 kilotons	Radar installations	900 m	38 percent	30 percent
1989				
W78; 335 kilotons	Hardened silos similar to those of SS-7/8/9s	0–225 m	74 percent	59 percent
W76; 200 kilotons	Radar installations	700 m	92 percent	74 percent

m=meters. *Not considering ABM system effectiveness. **HOB=height of burst

tack, or a Chinese attack with as many as 100 intermediate-range missiles. The Moscow ABM capability was diminished by the reduction of interceptors in 1979–1980 from 64 to 32.

The upgrade was formally completed in 1989 (but had significant problems and was not fully operational until 1995). It added 68 launchers for a total of 100, the maximum permitted under the Anti-Ballistic Missile Treaty. Four new launch sites were built closer to Moscow, with new Gazelle (ABM-3) interceptors (17 launchers each) based in hardened silos to strike reentry vehicles inside the atmosphere. The Gazelle has a range of 80 kilometers and carries a 10-kiloton warhead.

The improved surface-mounted Galosh (ABM-1B) interceptors, of which only 16 of the original 64 remained in 1987, were replaced with 32 long-range Gorgon (SH-11/ABM-4) interceptors, deployed in hardened silos to engage incoming reentry vehicles outside the atmosphere. In 1989, there were four Gorgon sites with eight silos each. The Gorgon has a range of about 350 kilometers and carries a 1-megaton warhead.

The A-135, which some claimed was a scaled-up version of the U.S. Nike-X system, included a new Pillbox phased-array radar with 360-degree coverage at Pushkino, northeast of Moscow. The Pillbox, which became fully operational in 1990, was connected to other radars to track incoming warheads and guide the interceptor missiles toward their targets. The Soviets upgraded the Hen House radar at Skrunda to a much more capable large phased-array radar (LPAR), and added another LPAR to the system at Pechora in the northeastern Urals.

A U.S. response to the Soviet upgrade

Given the Soviet ABM modernization, how might U.S. nuclear planners have targeted the new A-135 system in 1989? Unlike our 1968 case study, neither the number of weapons nor their characteristics have been declassified. But from what we know about 1968 planning, targeting methodology, and our calculations of the above strike, it is possible to make a reasonable guess.

Well before the A-135 was completed, the United States concluded that despite the improvements, "the system cannot presently cope with a massive attack."

"With only 100 interceptor missiles," the Pentagon explained, "the system can be saturated, and with only the single Pillbox radar at Pushkino providing support to these missiles, the system is highly vulnerable to suppression." Even so, the Pentagon acknowledged, "It does provide a defense against a limited attack or accidental launch."

For the nuclear planners, one of the most important features of the upgraded Soviet system was that the new Gazelle interceptors could engage ICBM and SLBM reentry vehicles *after* most pen-aids were lost during reentry through the atmosphere. This capability meant that more attacking warheads would be needed to defeat the ABM system.

To better calculate and predict the loss of warheads in an attack, U.S. nuclear planners in 1986 acquired a new tool—the multiple engagement model (MEM). Developed by the Joint Strategic Target Planning Staff in charge of the SIOP, the MEM simulates warhead attrition caused by ABM interceptors.

Because of their capability for surprise, we assume that SLBMs in 1989 were primarily used to target the radars, much like the 1968 plan. Unlike in 1968, however, the new Poseidon and Trident I C4 SLBMs were equipped with pen-aids. Moreover, we assume that individual SLBMs assigned to take out the radars had been downloaded to carry only a few warheads (see "Characteristics of U.S. Nuclear Weapons," p. 72).

In 1968, Soviet interceptors were "soft" aboveground targets, but in 1989 both the Gorgon and Gazelle interceptors were deployed underground in hardened silos. We don't know whether the silos were hardened to the same degree as ICBM silos, but assumed a low hardness similar to the SS-7, SS-8, and SS-9 missile silos. Using the vulnerability numbers from the declassified NTDI Handbook, and including the weapon system's reliability, we calculated the optimum height of burst and kill probabilities for Soviet ABM targets attacked by U.S. nuclear forces in 1989 (see "Optimized U.S. Nuclear Forces Attack," above).

This shows that it would require at least two W78 warheads from a

Minuteman III, detonated at 225 meters, to achieve a kill probability greater than 80 percent for each interceptor silo. For the softer radar installations, a single W76 warhead detonated at 700 meters would have a kill probability of 74 percent. We have therefore assumed that each silo would be targeted with one ICBM with at least two W78 warheads at surface or shallow burst (approximately 200 meters), and that each radar would be targeted with two airburst W76 warheads from an SLBM.

Because each Gorgon launch site included eight interceptor silos, and each Gazelle launch site had nine silos, to achieve a kill probability of more than 80 percent would require a staggering 16–18 warheads per launch site. As a result, we estimate that a 1989 strike against the Soviet ABM system would have required more than 100 ICBMs and SLBMs with more than 200 warheads, for a combined explosive power of 68 megatons (see "Projected U.S. ABM Suppression Strike, 1989," p. 77).

Radioactive fallout from airbursts over the radar facilities would be limited, but the use of many surface or near-surface bursts over the interceptor launch sites would create considerable fallout over Moscow and the surrounding areas. Calculations performed with a U.S. Defense Department computer program, using historical weather patterns for December, show that an unsheltered population in Moscow and outside the city to a distance of 35–75 miles would receive a lethal dose of up to 10,000 rem during the first 48 hours after the attack. The radioactive plume would be carried by prevailing winds for hundreds of miles (see "Fallout From Projected U.S. Attack, 1989," below).

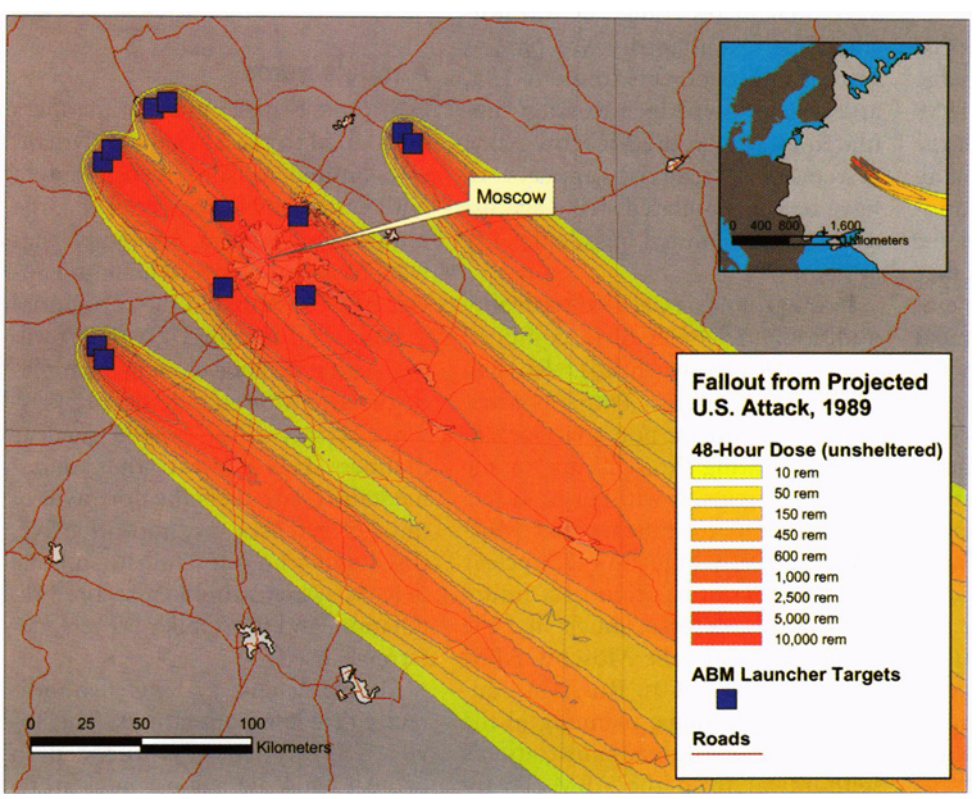
Modern anti-missile defense strike planning

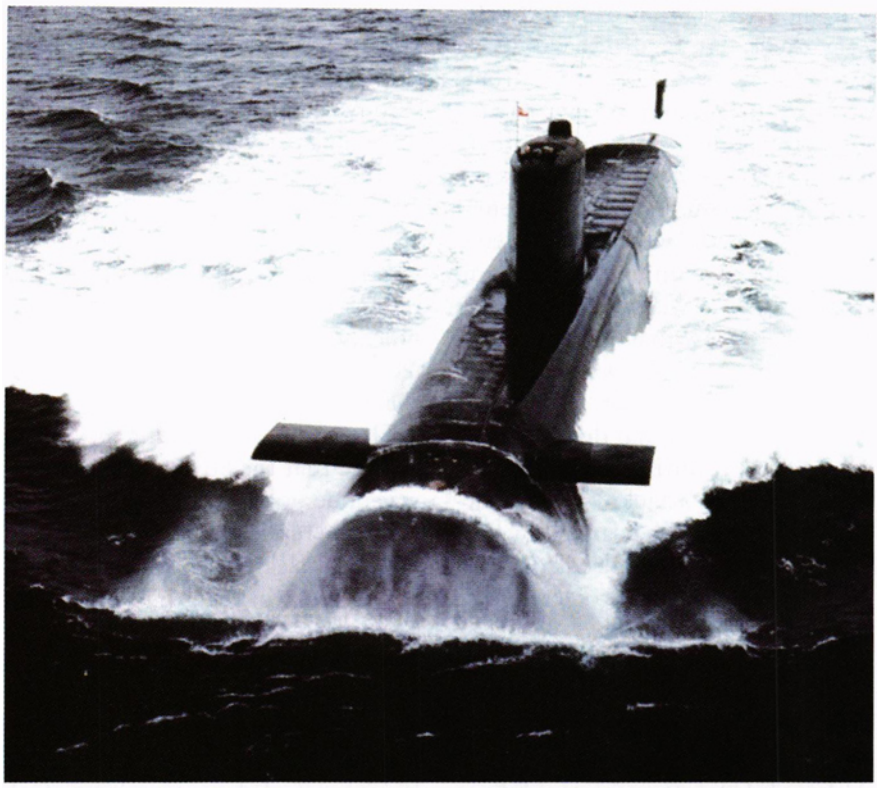
Although U.S. offensive capabilities have changed considerably since 1989 with the advent of the Peacekeeper ICBM and Trident II D5 SLBM, the basic ABM mission remains the same: to destroy the ABM system and then the Russian leadership targets in Moscow, and to ensure penetration of the main ICBM force against Russian silos to the south and east.

In the late 1990s, the effects of the Soviet Union's demise reduced Russian ABM capabilities. The Skrunda radar closed in 1998, leaving a significant gap in Russia's ability to detect submarine missiles launched in shallow trajectories.

The same year, signs began to emerge that the Soviet ABM system was undergoing a more fundamental change—replacement of some or all of the nuclear warheads with *conventional* warheads. In February 1998, the commander in chief of the Strategic Rocket Forces said that the system needed some minor modifications, but that the "nuclear umbrella" over Moscow would once again be opened. A few days later, Col. Gen. Vladimir Yakovlev, commander in chief of strategic missile forces, suddenly declared that the ABM system, with conventional warheads on the Gorgon and Gazelle interceptors, was combat-ready and would be placed on 24-hour alert status.

Shortly thereafter, Gen. Eugene Habiger, U.S. commander of Stratcom, bluntly told reporters: "I'm at odds with the intelligence community regarding the ABM system around Moscow, in terms of its capability. . . . My view is the system is not as capable as the intelligence community says." Habiger added, "The Russians have told me that the system is no longer operational." Two months later, retired Russian generals told a conference in Washington, D.C., that Russia had removed the nuclear warheads from its ABM interceptors and replaced them with conventional warheads.





Britain's *Resolution* was armed with nuclear-capable Polaris missiles.

Armada International echoed this in April 2002, reporting that the A-135 system was stood down briefly in 1997–1998 for that purpose.

In contrast with these reports, British Defence Minister George Robertson wrote in late January 1989 to a member of Parliament about the status of the Russian ABM system: "We assess that the Moscow anti-ballistic missile system comprising the short range Gazelle and longer range Gorgon interceptors remains operational and effective. . . . Deployment of any significant upgrades in the near future appears unlikely."

Whether or not the system is still nuclear armed, it appears operational. In November 1999, Russia launched an unarmed Gazelle interceptor from the Moscow system in the first test launch since 1993. The U.S. State Department said the test was "distressing," and that "Russia is raising the specter of an arms competition when what we're trying to do is work cooperatively with them to focus on rogue states."

A second test followed in October 2002, when a long-range Gorgon interceptor was launched from the Sary Shagan test range in Kazakhstan. The test allegedly was part of further improvements to the A-135, and was followed by a Russian simulated attack on the Moscow ABM system. The exercise appears to have been a simulated strike against a future U.S. limited missile defense system.

In 2003, Russia decided to deploy additional SS-19 ICBMs equipped with MIRVed warheads. Russian President Vladimir Putin boasted that "their combat potential, including penetrating through any missile defense systems, is without peers."

This seems to indicate that Moscow is already adjusting its nuclear planning in anticipation of a future U.S. missile defense, much like the U.S. response to the Moscow ABM system in the 1960s. Russia is conducting its strategic planning in the context of the Bush administration's withdrawal from the ABM Treaty and construction of a 100-interceptor missile defense.

And despite the newly declared partnership with Russia, U.S. nuclear planners appear to be refining their nuclear-strike planning against the Russian ABM system. In November 2003, Stratcom initiated a new round of upgrades to its ABM attack-simulation program.

Major U.S. early warning radars are deployed at Thule, Greenland, and Fylingdales, England. (Additional facilities are scheduled to be built in Japan.) If these sites are not already considered high-value targets as central components of a missile defense system, they soon would be—just like the Soviet ABM radars, which became priority targets for U.S. planners.

An upgrade to the Thule and Fylingdales radars is part of the Bush administration's missile defense effort. Whether these facilities might be targets has created some debate in both countries, but the British and Danish governments have both dismissed the risks and agreed to support the Bush plan.

A mug's game

U.S. (and British) nuclear planners responded to the Soviet deployment of a limited missile defense system with enormous firepower. The large number of nuclear weapons that were assigned to overwhelm the Soviet ABM system and the substantial technical efforts the U.S. undertook to defeat it provide chilling examples of the attention missile defense systems attract from hostile nuclear planners. It is a history that fundamentally contradicts the portrayal of missile defenses as non-offensive, threatening no one. Ballistic missile defense systems threaten secured retaliation, and for smaller powers, deterrence itself.

Missile defense systems also indirectly threaten populations. The Soviet ABM system was intended to protect Moscow against nuclear at-

ROYAL NAVY

tacks, but rather than shielding the capital from nuclear peril, the system in fact had the opposite effect of attracting nuclear warheads. Many other facilities would have been targeted in addition to the ABM system, including political and military leadership targets. "We must have targeted Moscow with 400 weapons," a former Stratcom commander has stated.

What is the relevance of this today? One could argue that all of this occurred during the Cold War, that U.S.–Soviet/Russian strategic competition is over, and that smaller nuclear powers do not have enough nuclear weapons to overwhelm missile defense systems. That may or may not be so. But at the superpower level, the action-reaction momentum seems to continue.

The United States apparently still targets the Moscow ABM system, and Russia appears to have begun adjusting its own forces to a future U.S. missile defense. The Bush administration's claim that its system will not be of concern to Russia may be true in a hypothetical Russian first-strike scenario with hundreds of missiles. But Russian planners are likely to be much more concerned with the effect on their surviving retaliatory capability after a hypothetical U.S. first strike has reduced the number of operational missiles. This will almost certainly drive new modernization efforts, newfound U.S.-Russian partnership or not.

For China, the situation is drastically different. The credibility of its nuclear retaliatory deterrent will be fundamentally challenged by a U.S. missile defense system. Ironically, the situation is similar to that in the late 1960s, when China was the "rogue" state used as the justification to build the first limited U.S. missile defense system. Back then, a system with 100 interceptors, the same capacity planned by the Bush administration today, was thought to be capable of reducing U.S. fatalities from a Chinese attack to "possibly zero, if the number [of Chinese missiles] does not reach 25." China today has approximately 20 ICBMs capable of hitting the U.S. mainland.

The current Chinese modernization program began more than a decade ago. The U.S. intelligence community estimates that by 2015, China will increase "several fold" the number of warheads primarily targeted against the United States. The Bush administration's claim that China will continue to modernize whether or not the United States builds missile defenses is a dangerous gamble that ignores the magnitude of the impact on the Chinese deterrent. "That impact will lessen if, as expected, China increases strategic nuclear arms over the next decade," said Stratcom commander Adm. James Ellis in 2001. But the U.S. experience with targeting Soviet missile defenses suggests that even the 75–100 warheads the U.S. intelligence community predicts China will have by 2015 may not be enough for it. The United States needed well over 100 missiles with even more warheads, pen-aids, and SSBNs to overwhelm the 1968 Soviet ABM system. The Chinese reaction to a more capable U.S. missile defense may spark similar changes in China's capabilities, as the CIA predicts: "MIRVing and missile defense countermeasures would be factors in the ultimate size of the force."

In the longer run, a missile defense system could also cause a doctrinal change, prompting China to abandon its purely retaliatory posture and replace it with counterforce targeting similar to that of the United States and Russia. As Admiral Ellis explained, "the more effective a U.S. missile defense system is in diminishing [the] retaliatory capability of Russian and Chinese deterrent forces, the greater the incentive for expansion of these forces to maintain their perceived deterrent effect."

The dynamics of nuclear competition and the history of the U.S. targeting of the Soviet ABM system remind us that missile defense systems are potent drivers of offensive nuclear planning. The missile defense that the Bush administration is building will be no exception, despite its limited capability, and it will almost certainly attract nuclear targeting from the start. ❋

Projected U.S. ABM suppression strike, 1989

Target	Weapon*		Warhead		Total	
	Type	No.	Type	Yield (kt)	Warheads	Yield (kt)
Moscow system						
Cat House radar	Trident I C4	1	W76	100	2	200
Dog House radar	Trident I C4	1	W76	100	2	200
4 Gorgon launch complexes	Minuteman III	32	W78	335	64	21,440
4 Gazelle launch complexes	Minuteman III	68	W78	335	136	45,560
Subtotal		*102*			*204*	*67,400*
Early warning radars**						
Hen House radar (Olenegorsk)	Trident I C4	1	W76	100	2	200
LPAR radar (Skrunda)	Trident I C4	1	W76	100	2	200
LPAR radar (Baranovichi)	Trident I C4	1	W76	100	2	200
Subtotal		*3*			*6*	*600*
Total		**105**			**210**	**68,000**

kt=kilotons. *We assume each Gorgon launch complex was targeted by eight Minuteman III missiles, each carrying two 335-kiloton W78 warheads; that each Gazelle complex was targeted by nine Minuteman III missiles, also each carrying two W78s; and that each Trident was downloaded to at least two warheads. Both Moscow radars could also be targeted by warheads from a single missile. **The LPAR and Pillbox radars at Pechora and Moscow, respectively, were under construction in 1989, and would later be targeted as well.

Attachment 24

April 2010

Still Poisoning the Well

Atrazine Continues to Contaminate Surface Water and Drinking Water in the United States

Authors

Mae Wu

Mayra Quirindongo

Jennifer Sass

Andrew Wetzler

NRDC

The Earth's Best Defense

About NRDC

The Natural Resources Defense Council (NRDC) is a national nonprofit environmental organization with more than 1.3 million members and online activists. Since 1970, our lawyers, scientists, and other environmental specialists have worked to protect the world's natural resources, public health, and the environment. NRDC has offices in New York City, Washington, D.C., Los Angeles, San Francisco, Chicago, Montana, and Beijing. Visit us at www.nrdc.org.

Acknowledgments

The Natural Resources Defense Council gratefully acknowledges the Park Foundation for its generous support of our work. The authors would also like to thank those people that provided review and comments on this report, including NRDC scientific staff and scientific experts from government and academia.

NRDC Director of Communications: Phil Gutis
NRDC Deputy Director of Communications: Lisa Goffredi
NRDC Publications Director: Anthony Clark
Production: Tanja Bos, tanja@bospoint.com

Table of Contents

Executive Summary

Watersheds and drinking water systems across the nation remain at risk for contamination from the endocrine-disrupting pesticide atrazine. An herbicide linked to harm to wildlife and humans, atrazine is the most commonly detected pesticide in U.S. waters. Although banned in the European Union in 2004, atrazine is still one of the most widely used pesticides in the United States.

In our 2009 report, *Poisoning the Well*, NRDC obtained and analyzed results of surface water and drinking water monitoring data for atrazine and found pervasive contamination of watersheds and drinking water systems across the Midwest and Southern United States. This new report summarizes scientific information that has emerged since the publication of our initial report. Findings based upon updated monitoring data on the presence of atrazine in surface water and drinking water draw attention to the continuing problem of atrazine contamination and the insufficient efforts by the EPA to protect human health and the environment.

Pervasive Contamination of Watersheds and Drinking Water Continues

Watersheds

Our analysis of the atrazine monitoring data taken from twenty watersheds between 2007 and 2008 confirms that surfaces waters in the Midwestern United States continue to be pervasively contaminated with atrazine.

- All twenty watersheds showed detectable levels of atrazine, and sixteen had average concentrations above 1 part per billion (ppb)—the level that has been shown to harm plants and wildlife.
- Eighteen of the monitored watersheds were intermittently severely contaminated with at least one sample above 20 ppb. Nine had a peak concentration above 50 ppb, and three watersheds had peak maximum concentrations exceeding 100 ppb.
- The Big Blue River watershed in Nebraska had the highest maximum concentration of any watershed tested—147.65 ppb, detected in May 2008.

Drinking Water

NRDC also analyzed atrazine monitoring data taken between 2005 and 2008 from drinking water systems located all across the United States. Our analysis paints an equally disturbing picture about drinking water contamination.

- 80 percent of the raw water (untreated) and finished water (ready for consumption) samples taken in 153 drinking water systems contained atrazine.

Atrazine has been detected in watersheds and drinking water systems across the Midwest and Southern United States. View maps of atrazine contamination online at **www.nrdc.org/health/atrazine/**

- Of the 153 drinking water systems monitored,100 systems had peak maximum concentrations of atrazine in their raw water that exceeded 3 ppb. Two-thirds of these 100 systems also had peak maximum concentrations of atrazine that exceeded 3 ppb in the finished water.
- Six water systems had high enough atrazine levels to exceed the EPA drinking water standard of 3 ppb.

These results represent only a sampling of public water systems in the United States. Thousands more drinking water systems may be unknowingly contaminated with atrazine, since the federal government only requires monitoring four times a year—compared to the more frequent weekly and bi-weekly monitoring data that we analyzed here. As such, the full extent of atrazine contamination of watersheds and drinking water systems across the United States is unknown.

Harm from Atrazine Exposure is Well Documented

The dangers associated with atrazine use have been well documented, and scientific data continue to emerge that further bolster the health concerns associated with atrazine exposure. The pesticide is an endocrine disruptor, impairs the immune system, and is associated with birth defects. The adverse effects of exposure to atrazine are particularly harmful during critical periods of development. And in the presence of other pesticides, atrazine works synergistically to increase the toxic effects stemming from expose to the harmful chemicals.

Current Regulations Do Not Adequately Protect Human Health

Two statutes principally govern the regulation of atrazine. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the EPA allows atrazine use both in agriculture (such as on corn, sorghum, and sugarcane) and at home (such as on lawns). Under the Safe Drinking Water Act, the EPA regulates the amount of atrazine that is allowed in drinking water. Specifically, only 3 ppb of atrazine (calculated based on a running annual average) is permitted in finished drinking water. NRDC believes a running annual average approach for drinking water is inadequate to protect human health, because even one-time exposures to developmental toxins like atrazine during critical periods of development may cause harm.

Our analysis of the data reinforces the fact that the monitoring schedule, set by the drinking water regulations, fails to guard against high spikes in atrazine levels or even ensure that the EPA's annual average limit on atrazine contamination is not being exceeded. Because public water systems are only required to take one to four samples per year, they are likely to miss a lot of the high spikes that we found. This means both that the EPA is ignoring high spikes of atrazine in drinking water and that the running annual average of atrazine in a system may actually be higher than suggested by four samples. Even short-duration exposures to atrazine should be regulated by the EPA.

Atrazine Use Imposes High Costs on Drinking Water Systems

Several studies have concluded that atrazine use provides only minimal benefits to crop production. On the other hand, the cost of treating drinking water for atrazine can add high costs to municipalities that have to install expensive treatment technology to remove the contaminant. Small systems located around agricultural areas where atrazine is frequently used may be particularly vulnerable to contamination problems and must spend a significant portion of their budgets to protect their customers from atrazine exposure. Water systems spend tens of thousands of dollars per year to maintain treatment systems that remove contaminants such as atrazine.

Recommendations for Reducing Atrazine Contamination

NRDC called for the phase-out of atrazine because of its harm to wildlife and potentially to people and because it has minimal or no benefits for crop production. Programs to improve water monitoring and encourage farmers to reduce their atrazine use are important next steps for addressing the problem of atrazine contamination while the EPA helps farmers transition away from the use of this pesticide altogether. NRDC recommends the following steps be taken to reduce atrazine contamination in U.S. waters

and minimize its impacts on human health and the environment:

1. The United States should phase out the use of atrazine.
NRDC strongly recommends that atrazine be phased out of all uses in the United States, including home gardens and golf courses. Evidence of atrazine's toxic effects on sensitive wildlife species and its potential risk to human health is abundant. The monitoring data show that high contamination levels in the Midwestern and Southern United States are pervasive. There is little compelling evidence that atrazine is needed by farmers.

2. Farmers should take immediate interim steps to reduce their atrazine use.
Farmers should take immediate steps to reduce their use of atrazine, including increasing reliance on a variety of non-chemical techniques for weed control. These include crop rotation, the use of winter cover crops, alternating rows of different crops, and mechanical weed control methods. Additionally, timing fertilizer applications to coincide with periods of greatest nutrient uptake by crops can avoid unnecessary fertilizer use that would fuel weed growth.

3. The EPA should monitor all vulnerable watersheds and require all future monitoring plans to identify worst case scenarios.
The EPA should broaden the monitoring program to assess all watersheds identified as vulnerable. The monitoring data in this update represent less than 2 percent of all the watersheds that are at highest risk from atrazine contamination. Future monitoring plans should be designed to identify the worst case scenarios occurring in vulnerable watersheds and in public water systems. More frequent sampling and sampling after big rainstorms and after fields have been treated with atrazine is necessary to assess the impacts of atrazine use on waterways. Such monitoring would provide a much more realistic view of the actual severity of the atrazine problem.

4. The EPA should publish monitoring results for each watershed and public water system sampled.
Monitoring results on the watersheds and the public water systems that were sampled under the two different monitoring programs were first made available to NRDC through Freedom of Information Act (FOIA) requests and litigation. People who live downstream of atrazine-treated fields have a right to know about high levels of atrazine contamination in their watersheds or drinking water systems. A publicly available website posting sampling data as it is analyzed and that regularly reports spikes of atrazine contamination would be an important step in the right direction, providing accessible information to the public. An interactive map of the data used in *Poisoning the Well* on NRDC's website allows users to see both watershed and drinking water data closest to their homes in graphical form.[1] This format is an example of what the EPA could do.

5. The public should use home water filtration systems and demand transparency of information from their water utilities.
NRDC recommends that consumers concerned about atrazine contamination in their water use a simple and economical household water filter, such as one that fits on the tap. Consumers should make sure that the filter they choose is certified by NSF International to meet American National Standards Institute (ANSI) Standard 53 for atrazine. A list of NSF/ANSI53-certified drinking water filters is available at www.nsf.org/certified/dwtu.

Attachment 25

8/1/06 Harper's Bazaar 59
2006 WLNR 15210047

Harper's Bazaar

August 1, 2006

Volume 313; Issue 1875

It's not easy being green: are weed-killers turning frogs into hermaphrodites?

Souder, William

In the summer of 1997, Tyrone Hayes, a biologist at the University of California, Berkeley, accepted what seemed a harmless offer to join a panel of eight other scientists investigating the safety of the common weed-killer atrazine. The panel had been commissioned by atrazine's inventor and primary manufacturer, the Swiss-based chemical giant then called Novartis and since renamed Syngenta. The company wanted to know if its product threatened "non-target" organisms, including fish, reptiles, and amphibians--creatures whose fate had remained largely unexplored through the half century in which atrazine had become the most heavily used herbicide in the United States as well as one of its most widespread environmental contaminants.

Hayes himself was acutely interested in discovering the causes of a global decline in frog populations that had worried scientists since the early 1990s. Many of the hormones and genes that regulate reproduction and development and metabolism in frogs perform similar functions in people, making frogs important proxies for humans--nature's test animals in a changing world. Syngenta's concern was different. The Environmental Protection Agency had been ordered by Congress to "reregister" atrazine as part of a program to subject a large number of older pesticides to current safety testing, a process that required considerable new data.

Initially, Hayes was asked only to review the scientific literature for studies involving atrazine and frogs. The review turned up nothing, so Hayes designed an experiment to test atrazine directly on the animals. "I honestly thought that the compound wouldn't do anything," Hayes says. "There was no basis that I knew of for a hypothesis that it would. My concern was how it would look to my colleagues. Would it look like I had prostituted myself to a company to do studies that weren't going to produce anything?" Hayes took a vote among his students in the Department of Integrative Biology, some of whom were so anticorporate, he says, that they wouldn't go to Starbucks. But they agreed to do the experiment. Over the course of the next two and a half years, Syngenta paid Hayes's lab $250,000.

The experiment was similar to ones Hayes had performed many times before. Newly hatched tadpoles were reared in water containing atrazine in amounts ranging from .01 to 25 parts per billion (ppb) until the animals completed metamorphosis. The test animal was the African clawed frog, a species known as the "lab rat of amphibians" and typically referred to by its generic name, Xenopus. Once used in human pregnancy testing, Xenopus is easier to rear than native North American species, largely because it is entirely aquatic, can be readily force-bred, grows quickly through well-defined stages, and will eat almost any commercial animal feed. Hayes gives his tadpoles Purina Rabbit Chow.

In March 1999, Hayes and his students divided 900 Xenopus tadpoles among thirty small aquariums. Half of the tanks contained atrazine; the rest--the control tanks--did not. All the tanks were coded, so neither Hayes nor his students knew which animals were swimming in what dose. Every three days, the tanks were cleaned and the solutions replaced. After forty days, the tadpoles had become frogs. When Hayes examined the frogs, all the control animals were normal. So were all the females. But among the males that had been exposed to atrazine at concentrations of 1 ppb or more, about 80 percent had smaller than expected laryngeal dilator muscles--puny voice boxes.

Laryngeal muscle size is an important secondary sexual characteristic in frogs; male frogs rely on the strength and pitch of their mating calls to attract females. Male bullfrogs sometimes sit near a spring at the edge of a pond where the inflow of colder water constricts the larynx and lowers the tone of their call.

Examining the frogs more closely, Hayes was surprised to discover that about a third of the male frogs exposed to atrazine also had abnormal reproductive organs. Some had malformed or multiple sets of testes. Others had both testes and ovaries, sometimes in odd numbers. The co-occurrence of testes and ovaries is rare in vertebrates and rarer still in Xenopus. Yet in Hayes's experiment this morphology had been elicited at concentrations as low as .1 ppb, a tenth of the amount that altered their voice boxes. Such a dose is equivalent to a grain of salt dissolved in a ten-gallon aquarium. To put it another way, the federally established "safe" limit for atrazine in human drinking water is 3 ppb, thirty times the dose that turned some of Hayes's frogs into hermaphrodites.

Tyrone Hayes is five feet three and sturdy from years of predawn cycling and running. He has shoulder-length black hair, which he wears braided or in a ponytail, or, sometimes, swept back from his face in a stiff mane. Around the lab he's usually in shorts and a T-shirt, but for speaking engagements and faculty meetings, he favors a black suit, an iridescent tie, and dangly earrings. Hayes was born in 1967, in Columbia, South Carolina, where his father is a carpet layer. He attended Harvard, where he earned a summa cum laude for a thesis on how temperature influences development in wood frogs. In graduate school, at Berkeley, Hayes studied endocrinology, investigating the impact of environmental factors on frog hormones. At thirty-two, he became the youngest tenured professor in the department's history and was named a full professor three years later.

Hayes says that he was naive about how his findings would be received. After reporting his discovery to the other panelists studying atrazine, Hayes argued with them and with Syngenta for months about what to do next. There were protracted discussions about the statistical relevance of the voice-box data and

disagreements over the pace of follow-up studies. Hayes was asked for repeated revisions of the "final" report on his results. He saw all of this as an effort to discourage him from publishing his findings. In November 2000 he quit the panel. In his letter of resignation he complained that were he to remain on the team, "recent history suggests that I will spend a great deal of effort preparing reports that will not be finalized in a timely manner, let alone published." He added, "It will appear to my colleagues that I have been part of a plan to bury important data."

In fact, Hayes's contract with Syngenta's atrazine panel did not prevent him from publishing his research. There was, however, an implicit understanding that panel members--in addition to scientists at Syngenta--would review one another's work. Hayes worried that such consultation, which had already slowed him, would eventually paralyze his research. Hayes's colleagues, meanwhile, wondered at his impatience. "Tyrone is an interesting person," says Keith Solomon, a professor of environmental biology at the University of Guelph, in Ontario, who contines to serve on Syngenta's panel. "But he's in a hurry."

In January 2001 staff scientists from Syngenta visited Hayes at Berkeley in an attempt to get him to rejoin the team. The meeting, which included discussions of a direct arrangement with Syngenta in which Hayes would continue his work, did not go well. "I'm certain they would have had control," Hayes says. Hayes instead went forward with money he had obtained from Berkeley and the National Science Foundation. He repeated the Xenopus experiment two times, and in April 2002 he published his findings in the Proceedings of the National Academy of Sciences.

He also performed a series of similar experiments using a common native species, the northern leopard frog. Hayes found that doses of atrazine as low as .1 ppb again caused various degrees of "sex reversal" in about a third of the males, and that some of the animals also displayed a freakish abnormality that Hayes had not seen in Xenopus: eggs forming in their testes. In the summer of 2001, Hayes and his students conducted field surveys of wild leopard frogs at eight locations in the United States and found the same deformities they had seen in the lab. At a site on the North Platte River in eastern Wyoming, far from the nearest farmland, Hayes discovered high levels of atrazine in the water and gonad problems in 92 percent of the male leopard frogs. In October 2002 he published these findings in Nature. The following summer he returned to the North Platte and found the atrazine contamination much reduced and only 8 percent of the frogs abnormal. A year later he measured no atrazine in the water at the site, and all the frogs were normal. (Hayes believes that the river had been temporarily contaminated somewhere upstream.)

In his published articles, Hayes argued that atrazine activates a gene that produces an enzyme called aromatase, which converts testosterone to estradiol, the strongest of the naturally occurring estrogens. Elevated levels of aromatase, he proposed, could explain the males' stunted voice boxes and multiple, mismatched sex organs--as well as the fact that atrazine appeared to have no effect on the females. Hayes called the process "chemical castration and feminization." He was not surprised that the abnormalities he found were associated with extremely weak doses of atrazine; hormones, including testosterone and estradiol, typically function at very low concentrations. "If you're a toxicologist, this is a low-dose effect," Hayes says. "If you're an endocrinologist, it's a reasonable effect."

Chemical poisons tend to be more toxic as the dose increases the classic "linear" dose-response association. But chemicals that affect hormonal systems sometimes operate in nonlinear ways: In women, for example, estradiol is necessary to stimulate ovulation, but a large dose of estradiol--the amount contained in the birth control pill---cancels this effect.

The science of endocrine disruption, as chemical interference with hormones has been dubbed, is new and complex. Unlike acute toxins, which can kill an organism outright, endocrine disrupters cause subtle damage, such as reproductive-system abnormalities or conditions that can lead to cancer. Effects seen at very low doses but that do not occur at higher doses con found traditional toxicological assay techniques. In 1996, Congress directed the EPA to include endocrine-disruption studies as part of its safety screening of licensed chemicals, but a decade later the agency is still trying to develop standards for laboratory tests.

According to Bruce Blumberg, an associate professor of developmental and cell biology at the University of California, Irvine, scientists who study endocrine disruption often see dramatic biological effects when they expose cell cultures to weak chemical concentrations. Curiously, Blumberg says, research sponsored by chemical companies rarely detects such effects.

Atrazine is among the world's oldest and most effective herbicides--the aspirin of weed-killers. It was developed during a period of intense innovation in the chemical industry that began with the Second World War and the invention of 2,4-D, the first "selective" herbicide: it could kill weeds without killing the crops. (It was later mixed with 2,4,5-T by the military to make the decidedly nonselective defoliant Agent Orange.) Syngenta, a company with roots dating back a couple of centuries that also gave the world DDT and LSD, introduced atrazine to the market in 1959. The new chemical was far more selective than 2,4-D--it is nearly impossible to kill corn with the stuff--and it was an immediate hit with farmers. Syngenta does not divulge sales figures for individual products, but atrazine continues to contribute a significant portion of the company's U.S. revenues from selective herbicides, which last year totaled $1.9 billion worldwide.

Atrazine residues are not found in significant amounts in food. Nor is it especially poisonous to vertebrates; it's unlikely that you could dissolve enough atrazine in water to kill a frog. A handful of studies have linked atrazine exposure to increased incidences of cancer in humans, but many more studies have found no evidence of such a correlation. Hayes, for his part, believes that atrazine, because it may cause endocrine problems in people, could play an indirect role in cancer. Estrogen, he points out, is known to promote tumor growth; a current treatment for breast cancer involves a drug that inhibits the production of aromatase. "How can we take the risk of exposing people to something that does the opposite?" he asks. In 2000 the EPA--in a move that downgraded the agency's earlier concerns about atrazine and cancer--declared that the compound is "not likely to be carcinogenic to humans."

Nevertheless, a fraction of the nearly 80 million pounds of atrazine applied to crops in the United States every year ends up contaminating surface water, groundwater, rain, and even fog. In the spring, concentrations in rivers and streams in the Midwest frequently exceed 10 ppb, and Syngenta has twice

voluntarily reduced the suggested application rate for atrazine on corn, from four pounds per acre to three in 1990, and to two and a half in 1992. Although atrazine breaks down fairly quickly in, soil and shallow surface water, it is more stable in larger bodies of water and in underground aquifers. In 1999 and 2000 the EPA and the United States Geological Survey, measuring reservoirs in agricultural areas of a dozen states, found atrazine in posttreatment drinking-water samples collected from community water systems, in some cases at concentrations of more than 2 ppb. In 2003 the EPA reported that a survey of more than 14,000 water utilities, drawing water from wells in twenty-one states, had found that atrazine, where it previously had been detected, averaged about .55 ppb--more than five times the amount that caused abnormalities in Hayes's initial experiment. Because water can take years to percolate down into aquifers, atrazine would still be found in well water for decades even if use of the pesticide were halted today. That very concern led the European Union to ban atrazine in the fall of 2003.

People, unlike frogs, don't undergo critical developmental stages exposed to the elements, and frogs may be particularly sensitive to waterborne chemicals. Still, in the same year atrazine was banned in the European Union, an American epidemiologist named Shanna Swan, then at the University of Missouri School of Medicine, published research showing reduced semen quality in men exposed to pesticides. Swan compared men in Columbia, Missouri, with men living in Minneapolis. The Columbia group had about half as many moving sperm in their semen as their Minneapolis counterparts. Urine samples from the Columbia group showed significantly higher herbicide residues. Swan says few of the men in Columbia were farmers and that she suspects their exposure to pesticides was through drinking water contamination. Reduced semen quality is correlated not only with reduced fertility but also with testicular cancer. One of the pesticides Swan detected in the Missouri group was atrazine.

On April 16, 2002, the day Hayes's Xenopus study appeared in print, The Wall Street Journal published a brief article about it, in which Tim Pastoor, Syngenta's North American head of research for human safety health issues, described Hayes's findings as "inconclusive." Syngenta, the Journal reported, "considers the Hayes study to be 'preliminary work' that might have to be retracted as the result of more detailed testing." Two months later, Hayes's former colleagues on Syngenta's atrazine research panel issued a press release stating that two teams of scientists, working independently, had tried to replicate Hayes's results and failed. Both studies had been funded by Syngenta and were led by members of the atrazine research panel. One was overseen by James Carr, a biologist at Texas Tech University; the other by John Giesy, a zoologist at Michigan State University. Hayes was furious. "Saying they couldn't replicate my work is different from saying they didn't replicate it," he says.

Reproducibility is a hallmark of good science, and the charge that a researcher's work cannot be duplicated is serious. An experiment that can't be repeated implies either incompetence or fraud on the part of the original author. A perfectly replicated experiment should always yield the same result, in the same way that two identical columns of numbers will add up to the same total. In practice, many variables come into play and experiments are never exactly the same. But as became clear from the data and descriptions of their experiments later submitted to the EPA, both Carr and Giesy departed from Hayes's methods--and neither proved as skillful at the difficult task of rearing frogs. Giesy performed two key

experiments loosely modeled on Hayes's. In one of the experiments, more than three quarters of the frogs died. In both, the control tanks were accidentally contaminated with atrazine at concentrations averaging at least .1 ppb, rendering the results inconclusive. (Giesy says his experiments were no more contaminated than anyone else's and that he merely had reported the control levels more precisely.)

Carr had problems, too. His frogs had been overcrowded and underfed, and many of his tadpoles failed to achieve metamorphosis. Some that did took longer than usual to reach that stage. Carr did not test atrazine at concentrations of less than 1 ppb. Even so, his experiment did produce frogs with abnormal gonads, though he found the effect statistically significant only at 25 ppb--250 times the amount that caused abnormalities in Hayes's experiment. Ordinarily, the detection of a similar effect in an experiment that only approximates the original is considered evidence that the effect is "robust." (Carr did not respond to my requests for comment.)

In any case, Hayes's research had already caught the attention of the EPA. In April of 2002, Hayes had been contacted by Tom Steeger, a scientist in the agency's Office of Pesticide Programs, in Washington, who said in an email that it would be "imprudent" of the agency to ignore the "disturbing results" of Hayes's investigation. The following July, Steeger visited Hayes's lab, where the experiments on Xenopus and leopard frogs were under way. After Steeger returned to Washington, he exchanged dozens of emails with Hayes and other scientists on the atrazine panel and at Syngenta in an effort to determine who had gotten what right about frogs and atrazine.

The Environmental Protection Agency regulates pesticides under a law called the Federal Insecticide, Fungicide, and Rodenticide Act. Adopted by Congress in 1947 and extensively amended since, FIFRA is now a book-length set of rules, the most important of which is this: the EPA is supposed to weigh a pesticide's economic benefits against any "unreasonable adverse effects" it may have on the environment or on human health. In 1988, Congress adopted the provision to reregister pesticides that had been licensed before 1984.

The EPA does not actually investigate the economic benefits of any pesticide, nor does it usually conduct its own research on the safety of such compounds. When confronted with evidence that a pesticide has adverse effects, the EPA usually responds with a recommendation that the matter be studied further, and under the peculiar logic of pesticide regulation, it is the manufacturer and not the agency that is responsible for testing chemical products. (The EPA stipulates what kinds of studies are necessary and requires companies to submit raw data in addition to safety conclusions.)

One way to maintain the perception that a pesticide is safe is to take a very long time reviewing information suggesting it is not. The EPA routinely reframes questions about the safety of pesticides in such a way that they remain questions, and evidence of adverse effects usually results in a demand for more study. Pesticide makers are allowed extravagant amounts of time for such follow-up work. And because the companies know the EPA must carefully review every study they submit, pesticide makers can game the system by submitting flawed and inconclusive research. The EPA then judiciously pores over the new data, finds it wanting, and

asks for something more definitive. The oversight the agency thus exercises can be thought of as a kind of business service. The EPA helps chemical companies understand safety concerns in terms of overhead. The agency refers to pesticide makers as "registrants," a term that makes them sound like guests in a luxury hotel, which in some ways does not seem far from accurate.

The Bush Administration has a deserved reputation for hostility to environmental regulation, but the EPA's process for licensing pesticides has become less stringent over the course of many years, under both Republican and Democratic leaders. According to a knowledgeable former EPA official, the agency was more aggressive in restricting and banning pesticides in its early years. It remained more independent and "professional" under the first President Bush than it has since become. During the Clinton years, the former official said, the agency adopted a conciliatory attitude toward pesticide manufacturers in an effort to counter the perception that it was staffed by environmental zealots. At the same time, chemical companies were becoming more adept at forging alliances with farm advocacy groups, which have enormous clout in Washington and have learned how to turn the EPA's "data addiction" to their advantage. "Scientists culturally cannot say no to data," the former official said of the staff in the agency's pesticide program. "It's hard for them to make a decision about what's in front of them when there is a promise of more information in the future." Delay, of course, has decided economic benefits for pesticide makers.

Syngenta's crop-protection division, where Tim Pastoor works, is located in Greensboro, North Carolina, in a leafy, campus-like complex just off Interstate 40. Pastoor, a pleasant, sandy-haired toxicologist, says the regulatory onus on his company is immense--a research program without end. Hearing that work disparaged because it's funded by the company "drives me crazy," Pastoor says. "It's as if they"--the company's safety studies--"are tainted when they're not." In an effort to anticipate the kinds of studies the EPA is likely to request of them, companies like Syngenta often undertake expensive research independent of the regulatory review process. When the company decided to look at atrazine's effects on frogs, it was under no obligation to do so. Pastoor says that since the reregistration process began, in 1994, Syngenta has spent $30 million on atrazine research and submitted close to 200 studies to the EPA. "I can assure you that I'm not concerned about the safety of atrazine use," Pastoor says.

Atrazine is one of nearly 900 pesticides that the EPA identified for reregistration eighteen years ago. In 1994, when the compound was still considered a cancer risk, it was placed under "special review." Twelve years later, with the August deadline for a final decision on reregistration approaching and the special review set to be completed within a year, the EPA's file on atrazine has swollen to more than a million pages of documents. The pace of reevaluation might have been even slower had it not been for a series of deadlines imposed on the EPA by a court order stemming from a case brought against the agency in 1999 by the Natural Resources Defense Council.

The NRDC, a well-funded environmental advocacy group based in Washington, D.C., is frequently in court against the EPA. With respect to atrazine, the group has sued the EPA for violating provisions of FIFRA, the Endangered Species Act, the Food Quality Protection Act, and the Federal Advisory Committee Act. These are not tort cases: the NRDC has sued not for damages on its own behalf or anyone else's

but instead solely in an attempt to make the EPA follow the federal laws that govern its regulation of pesticides. Like the reregistration process itself, these court cases tend to drag on for years.

Aaron Colangelo, a slight and plainspoken thirty-one-year-old graduate of Harvard Law School and a principal litigator for the NRDC, says that the agency should have suspended atrazine in the spring of 2002, after Hayes published his first article. "There was certainly enough justification to do it," Colangelo says. In atrazine cases, he says, he has often found himself alone at the plaintiffs table across the aisle from attorneys for the EPA and Syngenta--despite the fact that the NRDC has never named the company as a defendant in any of its actions. The EPA apparently is not embarrassed to be joined in court by lawyers for a company that it is supposed to be regulating.

The NRDC has not been alone in urging the EPA to act against atrazine. In 2002 the attorneys general of New York and Connecticut asked the agency to ban atrazine. Judith Schreiber, chief scientist at the Environmental Protection Bureau in the New York Attorney General's Office, wrote a pointed letter to the EPA arguing that the agency's own review of atrazine risks for human health and the environment warranted cancellation of the pesticide. And she scolded the agency for ignoring Hayes's findings. The EPA had failed "to adequately consider the endocrine disruption and reproductive effects of atrazine," Schreiber wrote, adding that Hayes's aromatase theory suggested that atrazine could act through a "common mechanism among frogs, reptiles and mammals, including humans."

In the summer of 2002, Everett Wilson, chief of the U.S. Fish and Wildlife Service's Division of Environmental Quality, also complained to the EPA about atrazine. In a letter to the agency's chemical review manager, Wilson contended that atrazine could harm endangered species, especially amphibians, by interfering with their hormonal processes or by killing the aquatic plants and invertebrates that amphibians eat. Wilson cited the Barton Springs salamander, an endangered amphibian that is known to live only in a springfed pool in a park in downtown Austin, Texas. Water samples collected in Austin by the U.S. Geological Survey show that when it rains, atrazine from grass treatment contaminates the salamander's habitat in concentrations that are sometimes greater than .5 ppb. Unlike FIFRA, the Endangered Species Act, which was adopted by Congress in 1973, contains no provision for balancing adverse environmental outcomes against economic considerations; it simply prohibits harm to any of the more than 1,000 species on the endangered list.

In November 2002, Hayes proposed an experiment he believed could end debate over his findings: he offered to provide Xenopus specimens to three labs in order to run concurrent studies, one by him at Berkeley, one at a lab chosen by Syngenta, and the third at a lab selected by the EPA. Hayes said that he would train lab workers at all locations in protocols--including how to feed and care for the animals--at his own expense. At the experiments' conclusion, each lab would exchange a third of its animals with each of the other labs, allowing all three parties to examine one another's frogs for abnormalities.

The EPA and Syngenta declined Hayes's invitation to collaborate. Jim Carr said in an email that he was "in principle" not opposed to the idea, but complained that Hayes was insensitive to the fact that there were features of his experiment that

"we do not wish to repeat." Keith Solomon agreed, reminding his colleagues by email of their previous inability to raise frogs using Hayes's methods.

Hayes says that, even allowing for start-up time, these new experiments could have been completed in a matter of months. Instead, the EPA asked for further analysis of the extant data, in the form of white paper that would consider seventeen recent studies--published and unpublished--involving atrazine and amphibians, including research by Hayes, Carr, and Giesy. (Twelve of the projects had been sponsored by Syngenta.) This white paper would, in turn, be submitted to the EPA's Scientific Advisory Panel, a group of seven scientists whose job is to provide the agency with "independent, external, expert scientific peer review." In this case, the panel was to be expanded to fifteen scientists, and a public hearing--a standard feature of such reviews--was scheduled for June 2003.

The white paper--written by Tom Steeger with help from Joe Tietge, a biologist at the EPA's Mid-Continent Ecology Division, in Duluth, Minnesota, who had led the agency's investigation of deformed-frog incidents several years earlier--was never conceived as a means of deciding the safety of atrazine. It was, according to the EPA, an effort to determine "whether there is a need for additional data to characterize more fully atrazine's potential risk to amphibian species, and, if so, what data should be developed." In other words, the white paper was intended from the outset primarily to help the agency decide what further research should be done on atrazine. Hayes deduced as much, and complained to Steeger that the white paper would merely lead to a routine call for more study--and that inclusion of Syngenta's dubious research was an effort to "dilute" his own legitimate findings with "garbage."

Extraordinary attention was paid to the white paper's wording. In May 2003 it was reviewed by two departments at the White House, the Council on Environmental Quality and the Office of Management and Budget, both of which advise the president on environmental policy. According to the NRDC's Aaron Colangelo, this degree of executive-branch involvement in the oversight of a single pesticide registration was unprecedented.

On June 17, 2003, the Scientific Advisory Panel convened for a four-day public hearing at the Crowne Plaza Hotel in the shimmery Crystal City suburb of Washington, D.C. Unlike peer reviewers for scholarly journals, who are unpaid and free to make whatever comments they like about the research they are asked to evaluate, the advisory panel members worked within narrow guidelines in assessing the white paper. They were paid $400 a day, and, although panelists sign detailed financial-disclosure forms crafted to expose conflicts of interest, there is no prohibition against scientists serving on the panel who receive research funding from the EPA in other areas and who thus might be reluctant to criticize its findings.

In their assessment, Steeger and Tietge wrote that there was enough evidence to "establish the plausibility of a hypothesis that atrazine could affect amphibian development," but, because of flaws in all of the existing studies, the EPA could neither accept nor reject such a theory. They proposed that Syngenta conduct further research. In its report to the EPA, submitted in August 2003, the Scientific Advisory Panel agreed that more research was needed in order to understand the effects of atrazine on frog development. The panel added that the

existing data was sufficient to "warrant concern"--a conclusion only marginally more forceful than the white paper's ambiguous finding.

"I would never go on an EPA panel again," says Darcy Kelley, a biology professor at Columbia University who participated in the panel's deliberation, and who is a leading authority on sexual differentiation in Xenopus. "It's a curious process, which is run within a set of guidelines that guarantee nothing will be done." Kelley, who has visited the EPA's lab in Duluth, said she was puzzled that the agency hadn't tried to replicate Hayes's experiment and surprised that each of the seventeen studies was given equal weight in the EPA's evaluation. She found Hayes's research worrisome because hermaphroditism does not normally occur in Xenopus. "He had the most striking results I've seen in a long time," she said. "I'd have said if you want to err on the side of caution, then you should not re-license atrazine." But, as David Skelly, an ecologist at Yale University who was also on the panel, put it, the group was not permitted to reach such a "novel conclusion." Still, in its report, the panel noted that, with the exception of the two experiments by John Giesy at Michigan State, the laboratory studies all suggested that atrazine disrupts normal reproductive development in frogs. "The inability to detect gonadal abnormalities with atrazine exposure in (Giesy's experiments) should not detract from the positive results noted in the majority of the studies," the panel members wrote.

In the fall of 2003, the EPA concluded an interim reregistration of atrazine. In compliance with the recommendation of the advisory panel, the agency also ordered Syngenta to conduct additional experiments on frogs and atrazine. Two years later, in the summer of 2005, scientists at Syngenta began their initial testing of atrazine on Xenopus. They expect to have results by the end of this year, more than four years after Tyrone Hayes proposed the joint experiment that could have resolved the issue in a few months. Meanwhile, in all likelihood, the reregistration of atrazine will be finalized this August.

In January, Hayes published two new papers in Environmental Health Perspectives. In one paper, he showed that when frogs are exposed to atrazine in combination with other pesticides--as they are in the environment--the damage to the animals' hormonal systems is more severe than from exposure to atrazine alone. In the other, he reported that when male tadpoles are exposed to estradiol (or to a synthetic compound that suppresses testosterone) they develop the same kinds of gonadal abnormalities that are associated with atrazine--a finding, he argues, that provides further support for his theory of "chemical castration and feminization." Hayes has also been trying to figure out why some male frogs in his experiments fail to exhibit elevated levels of aromatase or gonadal abnormalities after being exposed to atrazine. (The reason, he thinks, may have something to do with natural differences in the rates at which the frogs develop.)

Although Syngenta's current research is not, strictly speaking, an attempt to replicate Hayes's work--the experiments involve alternative methods--Hayes says he has full confidence that they will find the same adverse effect. Different methods and different strains of Xenopus could result in somewhat different frequencies and patterns of abnormal gonadal development or even no deformities at all. But, Hayes says, he can think of no reason why the essential result would not be the same. He also knows of no reason why the EPA will not continue to do nothing as the testing moves on to another phase. "My view is that the EPA is never going to

take action on atrazine," Hayes says.

Legally, the EPA needn't find a threat to human health to ban atrazine. Adverse effects in the environment are sufficient for the agency to take action, and in the view of many biologists it makes little sense to see humans in isolation from the environment. The question of what direct effects, if any, atrazine has on human health will be hard to answer, and will likely depend on inferences drawn from studies of surrogate species. Such inferences are never certain. Vertebrate toxicology is a kind of Russian roulette: Some species get lucky when they're exposed to chemicals; some don't. Thalidomide--the sedative that caused horrific birth defects in human infants in forty-six countries half a century ago--was believed safe because tests showed it had no effect on rats. In the very same ecosystems where Tyrone Hayes has found abnormal northern leopard frogs, he has also discovered that a close relative of that species--the plains leopard frog--appears to be unaffected by atrazine. As is usually the case with environmental contaminants, the real-world experiment is already up and running.

William Souder is the author of A Plague of Frogs and, most recently, Under a Wild Sky: John James Audubon and the Making of The Birds of America, which was a finalist for the 2005 Pulitzer Prize in biography.

---- INDEX REFERENCES ----

COMPANY: CROWNE PLAZA HOTEL; SYNGENTA AG; NOVARTIS AG

NEWS SUBJECT: (Economics & Trade (1EC26))

INDUSTRY: (Animal Research & Animal Rights (1AN65); Bioethics (1BI56); Environmental (1EN24); Agriculture, Food & Beverage Regulatory (1AG56); Chemistry (1CH57); Agrochemicals (1AG08); Chemicals (1CH04); Environmental Regulatory (1EN91); Manufacturing (1MA74); Science (1SC89); Science & Engineering (1SC33); Healthcare (1HE06); Healthcare Policy (1HE46); Physical Science (1PH15); Nature & Wildlife (1NA75); Agriculture (1AG63); Pesticides (1PE12); Agriculture, Food & Beverage (1AG53))

REGION: (Americas (1AM92); North America (1NO39); Europe (1EU83); USA (1US73))

Language: EN

OTHER INDEXING: (Hayes, Tyron; Research) (BARTON SPRINGS; BERKELEY; BUSH ADMINISTRATION; COLUMBIA UNIVERSITY; CONGRESS; COUNCIL; CROWNE PLAZA HOTEL; DEPARTMENT OF INTEGRATIVE BIOLOGY; ENDANGERED SPECIES ACT; ENVIRONMENTAL; ENVIRONMENTAL HEALTH PERSPECTIVES; ENVIRONMENTAL PROTECTION AGENCY; ENVIRONMENTAL PROTECTION BUREAU; ENVIRONMENTAL QUALITY; EPA; EUROPEAN UNION; FEDERAL ADVISORY COMMITTEE; FEDERAL INSECTICIDE FUNGICIDE; FIFRA; FOOD QUALITY PROTECTION; HARVARD LAW SCHOOL; HAYES; JOURNAL; MICHIGAN STATE; MICHIGAN STATE UNIVERSITY; MISSOURI; NATIONAL ACADEMY OF SCIENCES; NATIONAL SCIENCE FOUNDATION; NATURAL RESOURCES DEFENSE COUNCIL; NOVARTIS; NRDC; OFFICE OF MANAGEMENT; SCIENTIFIC ADVISORY PANEL; SYNGENTA; TEXAS TECH UNIVERSITY; US FISH AND WILDLIFE SERVICE; US GEOLOGICAL SURVEY; UNIVERSITY OF CALIFORNIA; UNIVERSITY OF GUELPH; UNIVERSITY OF MISSOURI SCHOOL OF MEDICINE; WHITE HOUSE; YALE UNIVERSITY) (Aaron Colangelo; Blumberg; Bruce Blumberg; Budget; Carr; Clinton; Colangelo; Darcy Kelley; David Skelly;

Delay; Democratic; Ecology Division; Everett Wilson; Giesy; Hayes; Irvine; James Audubon; James Carr; Jim Carr; John Giesy; Judith Schreiber; Keith Solomon; Kelley; Legally; Newly; Ordinarily; Pastoor; Purina Rabbit Chow; Reproducibility; Schreiber; Scientists; Shanna Swan; Steeger; Swan; Syngenta; Thalidomide; Tim Pastoor; Tom Steeger; Twelve; Tyrone; Tyrone Hayes; Urine; William Souder; Wilson; Xenopus) (University of California (Officials and employees); Atrazine (Complications and side effects); Atrazine (Research); Frogs (Research); Frogs (Physiological aspects); Frogs (Statistics); Herbicides (Complications and side effects); Herbicides (Research)) (Science & research (310); Labor Distribution by Employer (680); Executive changes & profiles (540)) (California (1U9CA))

PRODUCT: Herbicides; Herbicide Preparations; Agricultural chemicals, not elsewhere classified; Pesticide and Other Agricultural Chemical Manufacturing2879600; 2879603

SIC: 2879

NAICS CODE: 32532

Word Count: 7249
8/1/06 HBAZAAR 59
END OF DOCUMENT

Attachment 26

Playing Chicken with Antibiotics:
Previously Undisclosed FDA Documents Show Antibiotic Feed Additives Don't Meet the Agency's Own Safety Standards

PREPARED BY:

Carmen Cordova, Ph.D.
Sustainable Livestock Science Fellow
Natural Resources Defense Council

Avinash Kar, J.D.
Attorney
Natural Resources Defense Council

The authors are grateful for the helpful comments of Tyler Smith, Robert Martin, Keeve Nachman, and Meghan Davis at the Johns Hopkins Center for a Livable Future, Steve Roach at Food Animal Concerns Trust (FACT) and Prof. Hiroshi Nikaido at University of California Berkeley.

The authors are also indebted to Jonathan Kaplan, Jen Sorenson, Christina Swanson, George Peridas, Miriam Rotkin-Ellman, Erik Olson, and Jackie Prange (NRDC) for their helpful advice and comments.

The authors wish to acknowledge the support of Maria Bowman, Mary Woolsey, Andrea Spacht, Aaron Forbath, and Erin Daly (NRDC) in preparation of this publication.

SUMMARY

Between 2001 and 2010, the United States Food and Drug Administration (FDA) quietly reviewed the safety of 30 penicillin and tetracycline antibiotic[i] feed additives[ii] approved for "nontherapeutic use" in livestock and poultry.[iii] Nontherapeutic use refers to using antibiotics for growth promotion or to prevent disease in typically crowded, often unsanitary conditions.[1] NRDC obtained the previously undisclosed review documents from the FDA as a result of a Freedom of Information Act (FOIA) request to the agency and subsequent litigation made necessary by FDA's failure to provide any of the requested documents.

FDA's scientific reviewers' findings show that *none* of these products would likely be approvable as new additives for nontherapeutic livestock use if submitted today, under current FDA guidelines. Eighteen of the 30 reviewed feed additives were deemed to pose a "high risk" of exposing humans to antibiotic-resistant bacteria through the food supply, based on the information available. The remainder lacked adequate data for the reviewers to make any determination and their safety remains unproven. In addition, FDA concluded in their review that at least 26 of the reviewed feed additives do not satisfy even the safety standards set by FDA in 1973.

To our knowledge, FDA has taken no action since the reviews to revoke approvals for any of these antibiotic feed additives (although two were voluntarily withdrawn by the drug manufacturer). The FDA does not disclose sales of specific animal drug products, and we have no information about the quantities of these specific antibiotic additives that were sold for livestock use or administered to food animals. However, we found evidence suggesting that at least nine of these additives are being marketed today, and all but the two voluntarily withdrawn additives remain approved for use today.

The significance of these findings extends far beyond the 30 antibiotic feed additives reviewed. FDA data indicate that the types of antibiotics in the reviewed additives—tetracyclines and penicillins—together make up nearly half of all the antibiotics used in animal agriculture. Other feed additives with these same antibiotics, including generics, that are approved for similar uses would likely pose a similar risk of promoting antibiotic resistance. This risk was recognized by FDA in 1977 when it proposed to withdraw approvals for animal feed additives containing penicillin and most tetracyclines.[2]

Furthermore, the use of tetracyclines and penicillins in animal feed is part of a larger problem of antibiotic overuse. Approximately 70 percent of all sales of medically important antibiotics in the United States are for livestock use.[3] Scientists have demonstrated that nontherapeutic use of antibiotics to raise livestock promotes drug-resistant bacteria that can migrate from livestock facilities and threaten public health. These bacteria can spread resistant traits to other bacteria, and some of these shared traits also can confer resistance to antibiotics used primarily in human medicine.[4]

Unfortunately, the FDA's failure to act on its own findings about the 30 reviewed antibiotic feed additives is part of a larger pattern of delay and inaction in tackling livestock drug use that goes back four decades. A recent voluntary policy adopted by FDA, "Guidance #213," recognizes the problem, but lacks meaningful requirements and seems unlikely to curb uses of the antibiotics reviewed here or any of the other problematic uses (for a number of reasons discussed further below). It is time for decisive action to help protect the public from the threat of antibiotic resistance. The FDA should:

1. Complete the decades-delayed process for withdrawing approval of penicillin and tetracyclines in animal feed, strictly limiting their use to treating sick animals and, in rare circumstances, to controlling disease outbreaks.
2. Initiate the process for withdrawing approval for all other classes of medically important antibiotics approved for nontherapeutic livestock use that are not shown to be safe.

In the face of the FDA's continued inaction, Congress, food industry leaders, and consumers should step in to demand change. Congress should insist on real regulation of livestock antibiotic use as outlined in the Preservation of Antibiotics for Medical Treatment Act (PAMTA) in the House of Representatives[5] and the Preventing Antibiotic Resistance Act (PARA) in the Senate.[6] In the meantime, large food companies and consumers can reduce livestock antibiotic use by choosing meat and poultry supplied by producers that promote antibiotic stewardship in the livestock and poultry industry.

i Here we use "antibiotic" to refer to all antibacterial agents, including both synthetic antibacterials and those produced from a natural source. For convenience, and based on common usage, we use "antibiotic" throughout.

ii For convenience, "antibiotic feed additives" refers throughout to drug products added to both feed and water.

iii Hereafter, for ease of use, "livestock and poultry" is referred to only as "livestock." Similarly, "livestock facilities" refers to both livestock and poultry facilities.

A BRIEF OVERVIEW OF ANTIBIOTICS, RESISTANCE, AND LIVESTOCK USE

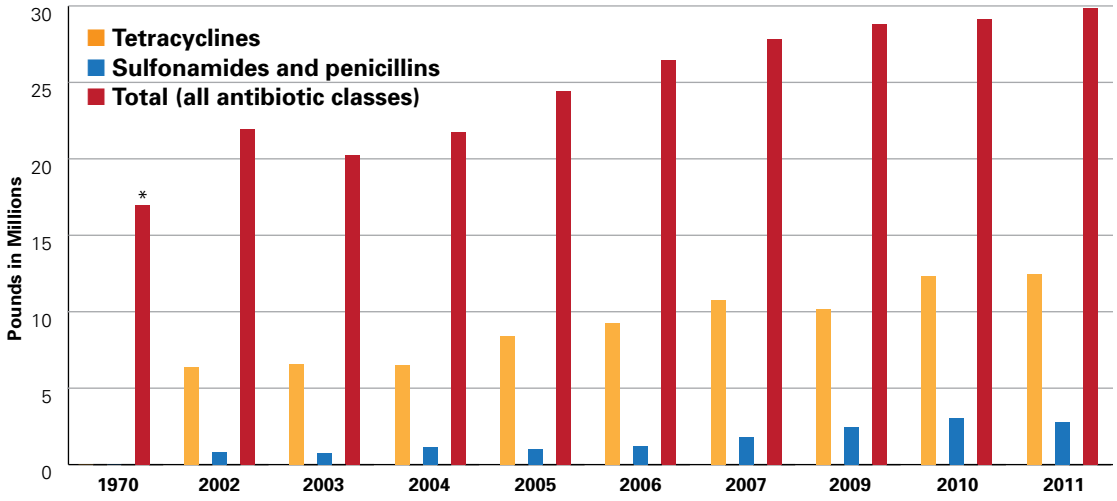
Antibiotics are the miracle drugs of the past century; they transformed medical care by turning infections that often proved fatal or required amputation into easy-to-treat illnesses.[7] Yet overuse and misuse of these medicines in both humans and food animals is causing rising rates of antibiotic resistance. The World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) have repeatedly highlighted the risk of an impending post-antibiotic era due to growing resistance and have called for action, including the curtailment of inappropriate uses in livestock.[8]

In a report on Antibiotic Resistance Threats in the United States, 2013, the CDC says that "[i]n most cases, antibiotic-resistant infections require prolonged and/or costlier treatments, extend hospital stays, necessitate additional doctor visits and healthcare use, and result in greater disability and death compared with infections that are easily treatable with antibiotics."[9] The agency also warns that declining effectiveness of antibiotics will undermine "many life-saving and life-improving" procedures and treatments, such as "joint replacements, organ transplants, cancer therapy, and treatment of chronic diseases such as diabetes, asthma, [and] rheumatoid arthritis."[10]

As U.S. production of meat and poultry products has grown, U.S. livestock farms have become larger, leading to more confinement and crowding and also to greater risk of disease among the animals.[11] After the FDA approved the use of antibiotics in livestock feed in 1951, producers began relying on nontherapeutic use of antibiotics to speed animal growth and to prevent disease.[12] Studies by both livestock scientists and advocacy groups, while they have data gaps, suggest that the majority of all antibiotic use in U.S. livestock is for these nontherapeutic purposes, rather than for the treatment of sick animals.[13]

Using antibiotics at low doses for extended periods of time in crowded livestock facilities can lead to more drug-resistant bacteria that can outcompete other bacteria, and escape livestock facilities to threaten human health.[14] A large chorus of scientists, health experts, and government agencies warns that the overuse and misuse of antibiotics in livestock production is contributing to the expanding public health crisis of antibiotic resistance, depleting the physician's arsenal of antibiotics effective for treating infections in people. In its recent report, CDC notes that "much of antibiotic use in animals is unnecessary and inappropriate and makes everyone less safe"[15] and emphasizes that antibiotic overuse in both human medicine and livestock production is contributing to the problem of resistance.[16] The report notes that antibiotic resistance is associated with at least 2 million illnesses and 23,000 deaths each year[17] and shows that as newer antibiotics become less effective, older antibiotics may matter more.[18]

Figure 1: Estimated use of tetracyclines and penicillins/sulfonamides from 1970 to 2011 in livestock production.



Numbers for 1970 and 2002-2011 are based on estimates from the FDA and quantities sold domestically as reported by AHI and to the FDA. Penicillin and sulfonamides were reported together.

* No estimate of penicillin and tetracycline use is available for 1970.

(Total=all antibiotic classes.)

Source: Data for graph compiled from several sources. Animal Health Institute, http://www.ahi.org/archives/2008/11/2007-antibiotics-sales/; The Poultry Site, http://www.thepoultrysite.com/poultrynews/7985/antibiotic-use-in-us-animals-rises-in-2004; Food and Drug Administration "Summary Report on Antimicrobial Sold for Food Producing Animals-2009," http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM231851.pdf; Food and Drug Administration, "Summary Report on Antimicrobial Sold for Food Producing Animals-2010," http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm277657.pdf; Food and Drug Administration, "Summary Report on Antimicrobial Sold for Food Producing Animals-2011," http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM338170.pdf; Food and Drug Administration, "Statement of Gregory J. Ahart, Director, Human Resources Division before the House Committee on Interstate and Foreign Commerce on Food and Drug Administration's Regulation of Antibiotics Used in Animal Feeds," http://www.gao.gov/assets/100/98536.pdf

PENICILLINS AND TETRACYCLINES: USE IN ANIMAL FEED AND FOR HUMAN HEALTH

The reviewed antibiotic additives—penicillins and tetracyclines—are also important for treating human disease. In the U.S. in 2011, penicillins accounted for 44 percent of the total antibiotics sold for human medicine, and tetracyclines accounted for 3.5 percent.[19] The World Health Organization lists penicillins as critically important for human medicine and lists tetracyclines as highly important.[20] The FDA itself recognizes both as highly important, even under its limited criteria whereby antibiotics are designated "critically important" only if the drugs are used to treat gut pathogens that cause foodborne illness.[21] A partial listing of continuing medical uses of these drugs is provided in Table 1, below.[22] Unfortunately, penicillins and tetracyclines are no longer effective in fighting some infections because of increased resistance, decreasing options for treatment.[23]

Table 1: Overview of common medical conditions treated with penicillins and tetracyclines

Antibiotic Class	Antibiotic	Common Uses in Human Medicine[24]
Penicillins	Penicillin G	Syphilis Bacterial meningitis
	Ampicillin	Bacterial meningitis Leptospirosis Complicated UTI (kidney complication)
Tetracyclines	Tetracycline	Eye infection Early stages of syphilis Ehrlichiosis (spread by ticks and fleas)
	Doxycycline*	Chlamydia Gonorrhea Bronchitis Tularemia Lyme Disease

*Specific antibiotic not used in livestock, but cross resistance between antibiotic used in livestock and this antibiotic has been observed.[25]

At the same time, tetracyclines and penicillins are among the most commonly used antibiotics in livestock production in the U.S. In 2011, 42 percent of antibiotics used in animals were tetracyclines and 6.5 percent were penicillins (Figure 1).[26]

ANTIBIOTIC-RESISTANT BACTERIA CAN ESCAPE LIVESTOCK FACILITIES TO THREATEN PUBLIC HEALTH

A rich body of scientific literature, reinforced by the latest CDC report on emerging antibiotic resistance, shows that antibiotic-resistant bacteria bred in livestock facilities can make their way off the farm in a number of ways. People who work with livestock or in meat production/processing can carry the resistant bacteria into their communities.[27] Resistant bacteria can travel from the farm in air or water, can wind up in the soil when manure is applied to crops, which in turn can end up on fruits and vegetables, and can be found in meat on retail shelves.[28] Even insects and rats can carry antibiotic-resistant bacteria from farms to surrounding communities.[29] There is mounting evidence that antibiotic-resistant bacteria that originate in livestock are reaching our communities and homes.[30]

Researchers have also demonstrated that the overuse and misuse of one antibiotic can actually lead to bacterial resistance to other antibiotics. This means that nontherapeutic use of penicillins and tetracyclines in animal feed can compromise the effectiveness of other medically important antibiotics that were not used in livestock facilities.[31] This occurs through mechanisms described by scientists as "cross resistance" or "co-resistance."[32] (See box on antibiotic resistance).

Antibiotic resistance: How antibiotic use increases the population of resistant bacteria

Mutation and multiplication

Bacteria multiply rapidly. Each time this happens, there is a small chance that a gene in a bacterium will mutate in a way that makes it resistant to a particular antibiotic.

While new resistance genes can and do arise, bacterial resistance and associated genes have long existed, although usually in very low numbers.[33] Using an antibiotic, for instance, for growth promotion and disease prevention purposes, allows resistant bacteria that can withstand the antibiotic to survive and multiply. This creates many new bacteria that carry the same resistance gene, while bacterial populations susceptible to antibiotics die off, and ultimately increases the overall population of antibiotic-resistant bacteria.[34]

Gene sharing and multiplication

Bacteria that are resistant to antibiotics can, in some cases, pass a resistance gene or 'trait' on to other bacteria, essentially "teaching" them how to endure an antibiotic. One or more resistance genes can be passed from one bacterium to another. This means that a bacterium can become resistant to an antibiotic it was never exposed to. This can even occur between different types of bacteria.[35] This gene-sharing can occur in any environment, including on the farm; in air, water, and soil; and in the community, including in the animal and human gut.[36]

Cross resistance: A resistance trait that confers resistance to multiple antibiotics

Sometimes a bacterium's ability to resist one antibiotic enables it to resist other antibiotics as well, even those it was not exposed to. In simple terms, a bacterium can figure out, and/or share with a neighbor, a way to fend off antibiotics that are similar in structure or mechanism. Resistance to drugs both within a class of antibiotics or across multiple classes of antibiotics can be shared in this way. For example, as indicated in Table 1, bacteria that are resistant to oxytetracycline can also be resistant to Doxycycline, another tetracycline used only in human medicine.[37]

Resistance traits that are shared can also confer resistance to drugs across antibiotic classes. A prime example of such a trait is the presence of antibiotic "pumps" in the bacteria. These literally pump out antibiotics from bacterial cells, and thereby make bacteria resistant.[38] Some of these pumps are very versatile and can pump out practically all classes of antibiotics currently used in medicine.[39] When this trait is transferred from one bacterium to another, the recipient bacterium can now withstand any antibiotic that the pump works on.

Co-resistance: Clusters of resistance traits that confer multidrug resistance

The ability of bacteria to move around and share genes also enables them to accumulate a cluster of resistant genes or traits in a single transferrable unit.[40] In one extreme case, ten resistance genes to eight different classes of antibiotics were found in such a unit.[41] This can lead to an increase in multidrug resistance in the population when even one of these antibiotics is used, resulting in the selection of bacteria that have received the cluster from their neighbors. For years the USDA, FDA, and CDC have been testing for several known clusters of resistant genes, such as the resistance (and transferable) unit ACSSuT (resistance to ampicillin, chloramphenicol, streptomycin, sulfonamides, and tetracycline), and such clusters are often detected.[42] The problem of co-resistant bacteria is well known in both livestock production and human medicine.

MAIN FINDINGS OF THE FDA REVIEW

NRDC obtained copies of the FDA review documents following litigation over a Freedom of Information Act (FOIA) request.[43] The documents tell a story of FDA's continuing inaction on antibiotic use in livestock even after the agency's own re-examination of 30 livestock antibiotic feed additives, some of which have been allowed for livestock use since the 1950s,[44] showed that these approved antibiotics have not been shown to be safe.[45] (For further details on the documents, see Appendix.) Starting in 2001 and concluding in 2010, FDA scientists, with expertise in fields such as veterinary medicine and microbiology, reviewed livestock antibiotic feed additives containing penicillin and/or tetracyclines.[46] The review was triggered by legislation in 2001 that set aside money for the FDA to work on antibiotics,[47] and was discontinued in 2010 for unknown reasons.[48]

The FDA scientists reviewed the livestock feed additives, listed by NADA (New Animal Drug Application) number in Appendix I, according to two sets of criteria: safety regulations adopted by FDA in 1973 and FDA's 2003 guidelines for evaluating the safety of new animal antibiotic drugs (see sidebar).

The findings of the FDA review are troubling. Of the 30 reviewed antibiotic feed additives, 26 have never met the safety criteria established by FDA in 1973.[49] The 1973 safety requirements mandated that drug manufacturers submit scientific studies that addressed several criteria, including evidence that establishes that the nontherapeutic use of the antibiotics in animal feed did not promote resistance to antibiotics used in human medicine (see sidebar).[50] In addition to the 26, three other antibiotic additives were found not to have met the 1973 safety requirements (and thus were not proven to be safe), although the requirements may not have applied.[51] Of the 30 reviewed feed additives, only one was found by FDA (in 1986) to meet the 1973 safety standards; however it was found to have failed the agency's standard for efficacy.[52] It too remains approved for use.

Furthermore, when these previously approved antibiotic feed additives were evaluated against the FDA's 2003 antimicrobial safety guidelines (Guidance #152) for the evaluation of a new animal drug,[53] the agency found that 18 of the 30 antibiotic feed additives posed a high risk of exposing humans to antibiotic-resistant bacteria through the food chain. While FDA did not have sufficient data to conduct a comprehensive risk assessment for any of the 30 additives, it did have enough information to conduct an abbreviated risk assessment for these 18 additives, which varied in the level of detail in the assessment. In all of these cases, FDA concluded that, based on the information available, these were "high risk" uses. For the remaining 12 additives, the drug manufacturers had not provided sufficient evidence for FDA to even determine the level of risk for human health posed by the additives, let alone to determine that the additives are safe as used (see Figure 1). Thus, none of the 30 reviewed feed additives could likely be approved in their current forms today.

Guidance #152 calls for the characterization of safety through the assessment of hazard (or level of risk) before approval of all new animal drugs. This allows the FDA to set the right restrictions for use of the drug in order to manage risk: under Guidance #152, high-risk drugs could only be approved for treatment of individual animals for short periods of time (less than 21 days).[54] Yet, the existing approvals for these 18 "high-risk" feed additives would allow much wider use. They are approved for over-the-counter use for long periods of time with no restriction on the number of animals to which they are administered. Thus, they could not be approved in their current forms today. The other 12 feed additives could not be approved today unless their safety was established[55] and FDA concluded that it did not even have sufficient information to estimate risk (see Appendix I).

The FDA has not withdrawn approvals for any of the reviewed antibiotic feed additives, even though the agency is required to do so when a drug is not proven to be safe.[56] FDA did send letters to "sponsors" (sponsoring company) in 2004 for six of these antibiotic feed additives deemed "high risk," requesting information to address concerns that the additives might promote antibiotic resistance (see Appendix III). The FDA records do not show that any of the sponsors provided additional studies that addressed the FDA's concerns (see Appendix III). Nor do the documents show that FDA took any further action.[57]

The FDA does not disclose sales of specific animal drug products, and we have no information about the quantities of these specific antibiotic additives that were sold for livestock use or administered to food animals. However, we found evidence suggesting that at least nine of these feed additives are being marketed today (see Appendix II), and all but two apparently voluntarily withdrawn additives remain approved for use today.[58]

FDA's Criteria for Evaluating the Safety of Approved Feed Additives

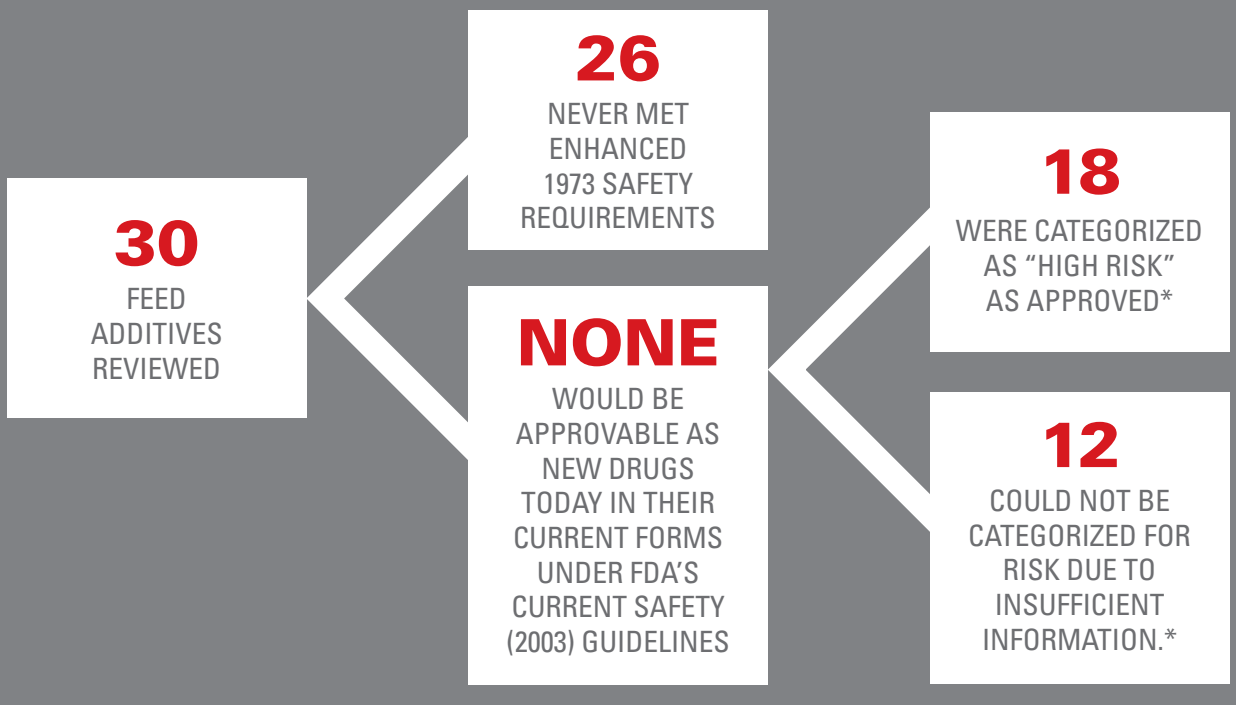
1973 Criteria (21 C.F.R. § 558.15)[59]
Beginning in 1973, the FDA required the submission of data to establish the safety of antibiotic use in animals for nontherapeutic purposes (growth promotion and disease prevention). Required submissions include studies demonstrating that the antibiotics feed additive does not promote resistance to antibiotics used in human medicine or increase *Salmonella* shedding in fecal matter when used in animal feed for growth promotion and disease prevention, as recommended by an FDA task force in 1972.

2003 Criteria (Guidance for Industry #152)[60]
The FDA's 2003 Guidance criteria evaluate antibiotic use on the basis of three parameters:

1. Risk that the antibiotic(s) added to feed will result in the emergence or selection of resistant bacteria in the animal being fed.
2. Likelihood of human exposure to a foodborne bacterium of human health concern.
3. Risk of adverse human health consequences if exposure occurs. This focuses primarily on the importance of the antibiotic class for human medicine and whether its effectiveness might be compromised.

The three factors above are combined to create a risk estimation of high, medium, and low. The criteria then describe allowed conditions of use for each of the different levels of risk such as restrictions on number of animals that can be treated at a time.

FDA Review of Approved Nontherapeutic Antibiotic Animal Feed Additives



* FDA must not approve or must withdraw approval for drugs that are not shown to be safe. [Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360b(d)(1)(B), (e)(1)(B).]

Example of FDA Inaction: Antibiotic Feed Additives That Continue to Be Sold Without Being Shown to Be Safe

CASE 1: Pennchlor SP 250/500: An antibiotic feed additive that made it to market without demonstrating safety relating to antimicrobial resistance.

The sponsor proposed but never submitted studies to address the 1973 safety criteria.[61] FDA's review does not mention any other studies that proved safety regarding the risk of antimicrobial resistance.[62] FDA sent a letter to the sponsor in 2004 because it concluded that the feed additive likely posed a "high risk" for promoting resistance in bacteria of human health concern and requested additional safety information.[63] Notably, FDA's letter focused only on growth promotion claims for the feed additive, even though prevention claims were approved for exactly the same kind of use that FDA had found not to have met safety criteria in the growth promotion context.[64,65,66] Both claims were approved with exactly the same restrictions (or lack thereof) on doses, dosage durations, and number of animals that can be treated.[67] There is nothing in the FDA documents that shows that the sponsor provided any new studies that addressed FDA's concerns.[68] FDA does not appear to have taken any action to withdraw approval even for the growth promotion claims it raised in its letter.[69] Today, Pennchlor SP250 continues to be marketed and is used in swine feeds.[70]

CASE 2: Penicillin G Procaine 50/100: An antibiotic feed additive that failed to meet safety criteria and is still marketed today.

In 1997, the FDA asked the sponsor to voluntarily withdraw this antibiotic additive due to increased concern from public officials and members of the health care community regarding the emergence of antimicrobial resistance.[71] In the same letter, the FDA stated that the product failed to meet antimicrobial-resistance safety criteria.[72] In its review, FDA noted increased microbial resistance was observed when the antibiotic feed additive was administered in feed to animals.[73] The sponsor apparently disputed this finding[74], yet the FDA documents do not contain any other studies to address the safety issue.[75] FDA sent another letter to the sponsor in 2004 laying out its concerns about resistance.[76] The record does not show that the sponsor submitted any new studies.[77] FDA never required the sponsor to take the antibiotic feed additive off the market, and it is still sold as a growth promoter in feed.[78]

Summary: Two medically important antibiotics in use in feed additives that have not been proven to be safe

Feed Additive name	Case I: Pennchlor SP 250/ Pennchlor SP 500	Case II: Penicillin G Procaine 50/100
NADA number	138-934	046-666
Antibiotic class in product	Penicillin, tetracycline, sulfonamides	Penicillin
Currently marketed by:	Pennfield Oil Co.[i]	Zoetis, Inc.[ii]
Approved for use in:	Swine	Non-laying chickens, turkeys, pheasants, and quail
Disease treatment and prevention:	Yes	No
Growth promotion:	Yes	Yes

i Pennfield Oil Co. is a large global animal health company. This company is not the original sponsoring company for the antibiotic feed additive.
ii Zoetis, a former business unit of Pfizer, is a large global animal health company. This company is not the original sponsoring company for the antibiotic feed additive.

HISTORY OF FDA INACTION

The failure to follow up on the recent review of antibiotic feed additives containing penicillin and/or tetracyclines is just the latest example of the FDA's inaction in the face of mounting evidence of public health threats stemming from the overuse and misuse of antibiotics in livestock. This inertia goes back four decades. In 1970, the FDA convened a task force of scientists from multiple agencies, including the National Institutes of Health, the U.S. Department of Agriculture, and the CDC, as well as from universities and industry. The task force found that the use of nontherapeutic antibiotics could threaten human health due to the likely rise of antibiotic resistance.[79]

Similar findings in the Swann Report, a 1969 report issued by the British government that inspired the creation of the FDA task force, had spurred Europe into action, leading to the removal of penicillin and tetracycline as growth promoters in animal feed in several European countries.[80] The European Union has since banned the use of all antibiotic growth promoters in animal feed, and Denmark has gone further to disallow prophylactic uses.[81]

Following the findings of the FDA task force, FDA adopted the 1973 regulations requiring drug manufacturers to prove the safety of using antibiotics in animal feed.[82] When drug manufacturers failed to establish safety pursuant to the 1973 regulations, in 1977, the FDA found that the use of penicillin and tetracyclines in animal feed was not shown to be safe and proposed to withdraw approval for those uses.[83] But the agency never followed through to complete the process. In 2012, NRDC sued to force the agency to act and won two court orders, including a directive to begin cancellation proceedings for penicillin and tetracyclines in animal feed.[84] The FDA then appealed. A decision is pending.

In 2003, the agency put out nonbinding guidelines (Guidance #152) that the agency follows in evaluating applications for new approvals of antibiotics for livestock use.[85] The 2003 guidelines were designed to increase the safety of new livestock drugs by reducing the likelihood that they would contribute to the development and spread of antibiotic-resistant bacteria via food. However, the 2003 guidelines do not apply to drugs that were previously approved, i.e., most of the antibiotics being used in livestock today.[86]

Since then, the agency has recently approved more voluntary guidelines (Guidance #213)—non-binding recommendations—to guide the use and marketing of previously approved livestock antibiotics.[87] A critical loophole is that while FDA's proposed guidelines would encourage drug manufacturers to discontinue selling drugs to speed up animal growth ("growth promotion"), it does not discourage the continuation of very similar or even identical uses as long as the intent is to prevent disease ("disease prevention"), even in cases where the animals are not sick and the use is driven by the anticipated effects of crowded and unsanitary conditions often found on livestock facilities. According to the FDA, "disease prevention involves the administration of an antimicrobial drug to animals, none of which are exhibiting clinical signs of disease, in a situation where disease is likely to occur if the drug is not administered."[88] Because many drugs are approved for both growth promotion and disease prevention uses,[89] most current uses can continue under a different label.

Action to Protect Public Health

The FDA should immediately move to end nontherapeutic uses of the reviewed penicillins and tetracyclines and should limit uses of these medicines to treat sick animals or, in rare cases, to control disease outbreaks. The drug manufacturers of these antibiotic feed additives have failed for four decades to prove that they are safe for human health, as they were required to by law.[90] And FDA has failed to withdraw approval for these drugs in that time, in spite of the drug manufacturers' failure to prove the safety of their products.

As described above, the public health risks found by the FDA's review of 30 antibiotic feed additives are an indicator of a larger threat. The nontherapeutic livestock use of other penicillins and tetracyclines—and, indeed, any other medically important antibiotics—poses a risk of breeding resistant bacteria and contributing to the spread of antibiotic resistance. The FDA should therefore move swiftly to take the necessary steps to eliminate all nontherapeutic uses of all classes of medically important antibiotics in livestock production. FDA should also require improved reporting on livestock antibiotics, including reporting by users of these antibiotics, to enable the agency to track progress in meeting this goal.

Congress must act

If the FDA fails to take action, then Congress should step in to ensure that these essential medicines continue to be effective for humans for as long as possible. It should pass the Preventing Antibiotic Resistance Act and the Preservation of Antibiotics for Medical Treatment Act, both of which would phase out the nontherapeutic use of medically important antibiotics in animal feed.

Food companies and consumers should not wait for federal policy reform

While federal policymakers continue to delay, consumers and business leaders can make progress in promoting antibiotic stewardship in the livestock industry. Consumers should purchase animal products labeled "Certified Organic" or "No Antibiotics Administered" when they can. Food companies with large purchasing power should specify antibiotic stewardship requirements for producers who supply them. While many livestock producers have innovative production systems that are not reliant on nontherapeutic antibiotic use, others must now acknowledge the risks of these practices and transition their operations away from antibiotic dependency.

METHODS

EVALUATION OF DOCUMENTS:

Four volumes of the FDA review were received and the volumes included short and long versions of product reviews of penicillin and tetracycline feed additives. The FDA review was carried out from 2001 to 2010 by the Microbial Food Safety Team (HFV 157) in the Office of New Animal Drug Evaluation. Each review (Microbiologist's review) included a brief summary, a review of the administrative record, and conclusions. Specifically, a review of the administrative record included assessment of 21 C.F.R. § 558.15 (1973 safety and efficacy criteria) information, and assessment of the administrative record using Guidance for the Industry (GFI) #152. Extra documentation was provided that pertained to studies addressing 21 CFR 558.15, email correspondence related to the review team, correspondence between the sponsor and the Center for Veterinary Medicine (CVM), as well as background literature and related presentations or posters. Information presented in Appendix I is based on the short and long versions of the product reviews by the Microbial Food Safety Team including summarized 21 CFR 558.15 information, summarized correspondence and conclusions made by the FDA review team.

EVIDENCE OF MARKETING:

NADA numbers were entered into the Animal Drugs @ FDA (database of Approved Animal Drug Products, http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/). The current sponsor was identified and a search was performed for any evidence of current marketing (including product inserts, MSDS sheets, summary information, etc.) In addition, a search was performed using either the NADA number or the proprietary name and evidence of inclusion in any current or recent catalogs was included as evidence. In one case evidence was found of a generic product based on an identified NADA in the FDA review. The Feed Additive Compendium contained names of several products listed in Appendix I. Because NADA numbers are not associated with those products in the Compendium and many products have similar names, results from the Feed Additive Compendium are not included in Appendix II.

EVIDENCE OF WITHDRAWAL:

NADA numbers were entered into the Animal Drugs @ FDA (database of Approved Animal Drug Products, http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/). NADA numbers were cross referenced to the FDA Green Book (Section 6: Voluntary Withdrawals and monthly updates to Jan. 2014, The current status of the drug was assessed and in cases of withdrawal by the sponsor, such a status was noted.

APPENDIX I

Compilation of FDA scientists' review of 30 penicillin and tetracycline feed additives regarding 1973 criteria and Guidance #152.

Name of product	Volume of FDA Review	NADA Number	Met 1973 Safety Criteria	1973 Safety Criteria Citation	Risk Estimation (Guidance 152)	Risk Citation	Additional Information
Terramycin Animal Formula, Soluble Powder	Vol. I	008-622[#ii]	Not met	FDA001732	High risk**[#i]	FDA001739	May not be applicable to 1973 criteria, Animal Drugs @FDA
Terramycin Type A medicated Articles	Vol. I	008-804	Met (in 1986)	FDA002102/ FDA002105/ FDA002110	Not enough information	FDA002114	
Aureomix Granular 500	Vol. II	035-688	Not met	See below	High risk**	FDA002145-002147	
(see above), Aureo S 700, Aureomycin	Vol. II	035-688, 035-805, 048-761	Not met	FDA002333	High risk**	FDA002325-002333	
Aureomix S 700 G	Vol. II	041-649	Not met	FDA003898	High risk	FDA003898	
Aureomix S 700 B	Vol. II	041-653	Not met	FDA003908-003910	Not enough information	FDA003910	
Penicillin 100/Penicillin G Procaine 50	Vol. II	046-666	Not met	FDA004026/FDA004029	High risk**	FDA004024-004027	
Pencillin G Procaine 50%	Vol. II	046-668	Not met	FDA004320-004322, FDA004324	High risk**	FDA004326-004330	
Chlormax products, Micro CTC 100	Vol. II	046-699	Not met	FDA004453-004454	High risk**	FDA004459	
Chlorachel 50, Pfichlor products	Vol. II	049-287	Not met	FDA0044486	High risk**	FDA004469-004476	
Rainbrook Broiler Premix No. 1	Vol. II	049-462	Not met	FDA004494	High risk**	FDA004491-004493	Withdrawn, Green book/Animal Drugs@ FDA

Name of product	Volume of FDA Review	NADA Number	Met 1973 Safety Criteria	1973 Safety Criteria Citation	Risk Estimation (Guidance 152)	Risk Citation	Additional Information
Aureomycin Soluble Powder	Vol. II	055-020#	Not met	FDA004521	Not enough information	FDA004522	May not be applicable to 1973 criteria, Animal Drugs @FDA
Penicillin G Potassium	Vol. II	055-060*	N/A	FDA004532	High risk	FDA004533-004536	1973 criteria not applicable FDA004533
Tetracycline Soluble Powder	Vol. III	065-496#	Not met	FDA007239	High risk**	FDA004619-004623	May not be applicable to 1973 criteria, Animal Drugs @FDA
ChlorMax SP products, Chlorachel 250	Vol. III	091-668	Not met	FDA004730	High risk**	FDA004724-04730	
CLTC 100 MR, CLTC 70	Vol. III	092-287	Not met	FDA004766	Not enough information	FDA004774	
OXTC products, Terramycin products	Vol. III	095-143	Not met	FDA004811	Not enough information	FDA004811-FDA004812	
Pfichlor 100S Milk Replacer	Vol. III	100-901	Not met	FDA004818	High risk	FDA004819	
Terramycin Premix	Vol. III	103-758	Not met	FDA004838	Not enough information	FDA004839	Withdrawn,[3] Animal Drugs@FDA
Pennchlor SP 250/ Pennchlor SP 500	Vol. III	138-934	Not met	FDA004849-004850, FDA004872	High risk**	FDA004872-004876	
Oxytetracycline products, Pennox products	Vol. III	138-938	Not met	FDA004898	Not enough information	FD004899-4902	
CSP 250/CSP 500	Vol. III	039-077	Not met	FDA006977	High risk**	FDA006973-006977	

Name of product	Volume of FDA Review	NADA Number	Met 1973 Safety Criteria	1973 Safety Criteria Citation	Risk Estimation (Guidance 152)	Risk Citation	Additional Information
Chloratet 100, Chloratet 90	Vol. III	048-480	Not met	FDA007160	High risk	FDA007160	
CLTC products	Vol. III	092-286	Not met	FDA007259	Not enough information	FDA007259	
Aureomix S 700-A, Aureomix S 700-D, Aureomix S 700-E, , Aureomix S 700-F, Aureomix S 700-H	Vol. III	041-647 041-648 041-650 041-651 041-654	Not met	FDA007294	Not enough information	FDA007294	
Quratermaster Dry Cow Treatment	Vol. III	055-028*	N/A	FDA007729	High risk**	FDA007729-007738	1973 criteria not applicable (Vol. III FDA007723)
Aureomix S 700-C 2	Vol. IV	041-652	Not met	FDA009391	High Risk	FDA009391	

APPENDIX II

EVIDENCE OF MARKETING

1. Pennchlor SP 250 (NADA 138-934) – evidence of marketing through a feed company

"Pennchlor SP 250 – Product Description," Feed Products and Company South, http://www.feedproducts.net/products/pennchlor-SP-250.htm, accessed November 25, 2013.

"Pennchlor SP-250- Specifications," Feed Products and Company South, http://www.feedproducts.net/documents/PennchlorSP250.pdf, accessed November 24, 2013.

2. Aureomix 500 (NADA 035-688) – evidence of marketing through an animal pharmaceutical company

"Product inserts – Aureomix 500," Zoetis, https://online.zoetis.com/US/EN/contact/product_information/Pages/ProductInserts.aspx, accessed November 25, 2013.

"Material Safety Data Sheet," Zoetis, https://online.zoetis.com/US/EN/MSDS_PI/PI/Aureomix_500.pdf, accessed November 25, 2013.

3. Penicillin 100 (NADA 046-666) – evidence of marketing through an animal pharmaceutical company

"Product inserts – Penicillin 100," Zoetis, https://online.zoetis.com/US/EN/contact/product_information/Pages/ProductInserts.aspx, accessed November 26, 2013.

"Material Safety Data Sheet," Zoetis, https://online.zoetis.com/US/EN/MSDS_PI/PI/Penicillin_100.pdf, accessed November 25, 2013.

4. Chloratet (NADA 048-480) – evidence of marketing through a supplier company

"PALS feed additives and medication products catalog" PALS USA, http://palsusa.com/files/PALSMedCatalog.pdf, last accessed November 21, 2013.

5. Terramycin (NADA 008-622) – evidence of marketing of the generic (ANADA 200-026) based on this NADA by a supplier company

"Supplemental Abbreviated New Animal Drug Application" Food and Drug Administration, http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm061570.pdf, last accessed on November 24, 2013.

"Terramycin 343-soluble powder" Revival Animal Health, http://www.revivalanimal.com/Terramycin-343-Soluble-Powder-Generic.html, last accessed on November 25, 2013.

6. Aureomycin NADA (48-761) – evidence of marketing by an animal pharmaceutical company

"Product insert - Aureomycin 50, 90, 100 Granular," Zoetis, https://online.zoetis.com/US/EN/contact/product_information/Pages/ProductInserts.aspx, accessed November 25, 2013.

"Material Safety Data Sheet," Zoetis, https://online.zoetis.com/US/EN/MSDS_PI/PI/Aureomycin_50_90_100_Granular-swine.pdf, accessed November 25, 2013.

7. Pennox 100MR (NADA 138-938) – Evidence of marketing by a supplier

"Pennox 100MR – Product Description," Feed Products and Company South, http://www.feedproducts.net/products/pennox-100-MR.htm, accessed November 25, 2013.

"Pennox 100MR- Specifications," Feed Products and Company South, last modified October 2010, http://www.feedproducts.net/documents/Pennox100MR.pdf, accessed November 24, 2013.

8. CLTC (NADA 92-287) – Evidence of marketing by a supplier and by inclusion in a USDA risk management program

"CLTC-100 MR" Animart Dairy and Livestock solutions, http://www.animart.com/store/cltc-100-mr-50lb-drum/, accessed November 24, 2013.

"CLTC 100MR" Food Animal Residue Avoidance Databank, http://www.farad.org/vetgram/ProductInfo.asp?byNada=092-287, accessed November 24, 2013.

9. Chlormax (NADA 46-669) – Evidence of marketing by an animal pharmaceutical company

"Product inserts – Chlormax," Zoetishttps://online.zoetis.com/US/EN/contact/product_information/Pages/ProductInserts.aspx, accessed November 25, 2013.

"Material Safety Data Sheet," Zoetis, https://online.zoetis.com/US/EN/PublishingImages/Poultry%20Literature%20Library/US-EN/ChlorMax_Product_Profile_ZP130030_EN_Zoetis.pdf, accessed November 25, 2013.

Note: All products above are also listed by brand name in Feed Additive Compendium.

APPENDIX III

Selection of correspondence between Center for Veterinary Medicine and sponsors on FDA review conclusions.

NADA 046-666

Excerpt from letter sent to sponsor: "The administrative record does not contain sufficient information to alleviate the Center [for Veterinary Medicine]'s concern about the use of your product and its possible role in the emergence and dissemination of antimicrobial resistance."
Food and Drug Administration, Letter from FDA to Sponsor of NADA 046-666, May 26, 2004, Vol. III: FDA007516.

Excerpt from sponsor response: "[W]e wish to advise CVM of our strongly held view that these products, with the current claims, remain safe and effective…. The amendment to the FY 2001 appropriation directed a review of previous approvals. It did not alter the standards applicable to withdrawing approval to allow withdrawal based on nonscientifically based precautionary grounds. We believe the agency should be able to separate the justifiable concerns related to the development of antibiotic resistant human pathogens and discern that [the sponsor's] subtherapeutic penicillins are not the source of, or even a measurable contributor to, this public health issue."
Food and Drug Administration, Letter from Sponsor (of NADA 046-666, 035-688 039-077, and 091-668) to FDA, October 22, 2004, Vol. III: FDA008180-2.[iv] *Note: The sponsoring company sent the same letter as a response to FDA's letters regarding four separate NADAs.*

NADA 046-668

Excerpt from letter sent to sponsor: "The administrative record does not contain sufficient information to alleviate the Center [for Veterinary Medicine]'s concern about the use of your product and its possible role in the emergence and dissemination of antimicrobial resistance."
Food and Drug Administration, Letter from FDA to Sponsor of NADA 046-668, received May 26, 2004, Vol. III: FDA007518.

Excerpt from the sponsor response: "[The sponsor] has been unable to make a decision on how to proceed on this issue. Although [Center for Veterinary Medicine] did supply us with a copy of the presentation given at the meeting, very little information was presented on the hazard characterization. In addition, it would be helpful for us to see a more complete description of the risk assessment so that we can determine what additional data may be collected/supplied to help support a more thorough evaluation."
Food and Drug Administration, Letter from Sponsor (of NADA 046-668) to FDA, November 15, 2004, Vol. III: FDA008950.

NADAs 035-688, 039-077, 091-668

Excerpt from letter sent to sponsor: "The administrative record does not contain sufficient information to alleviate the Center [for Veterinary Medicine]'s concern about the use of your product and its possible role in the emergence and dissemination of antimicrobial resistance."
Food and Drug Administration, Letter from FDA to Sponsor of NADA 035-688, 039-077, and 091-668, May 26, 2004, Vol. III: FDA007522.

Excerpt from sponsor response: … We wish to advise CVM of our strongly held view that these products, with the current claims, remain safe and effective… The amendment to the FY 2001 appropriation directed a review of previous approvals. It did not alter the standards applicable to withdrawing approval to allow withdrawal based on nonscientifically based precautionary grounds. We believe the agency should be able to separate the justifiable concerns related to the development of antibiotic resistant human pathogens and discern that [the sponsor's] subtherapeutic penicillins are not the source of, or even a measurable contributor to, this public health issue."
Food and Drug Administration, Letter from Sponsor (of NADA 046-666, 035-688 039-077, and 091-668) to FDA, October 22, 2004, Vol. III: FDA008180-2.[iv]

NADA 138-934

Excerpt from letter sent to sponsor: "The administrative record does not contain sufficient information to alleviate the Center [for Veterinary Medicine]'s concern about the use of your product and its possible role in the emergence and dissemination of antimicrobial resistance."
Food and Drug Administration, Letter from FDA to Sponsor of NADA 138-934, May 26, 2004, Vol. III: FDA007526.

Excerpt of FDA's summary of the sponsor's response: "The firm submitted a letter dated July 31, 2006 stating that they would remove the 'growth promotion and increased feed efficiency' indication from their label, as long as the other firms with the same product and indication did so as well…The firms also submitted (January 4, 2005) the results of a literature search… Specific information to address the data gaps in the microbial food safety assessment was not retrieved by the search terms used by the firm."
Food and Drug Administration, Microbial Food Safety Team (HFV-157), Brown Amendment Review of NADA 138-934, Vol. III: FDA004849-50

Endnotes

1 As noted, we use the term "nontherapeutic use" to refer to the use of antibiotics to speed up animal growth and prevent diseases. Antibiotics are typically administered for these purposes to large groups of animals for extended periods of time. We use "therapeutic" use to mean the use of antibiotics to treat sick animals or to control disease outbreaks in rare circumstances. FDA regulations refer to growth promotion and disease prevention uses as "subtherapeutic." 21 C.F.R. § 558.15.

2 Penicillin-Containing Premixes Notice, 42 Fed. Reg. 43,772 (Aug. 30, 1977); Tetracycline (Chlortetracycline and Oxytetracycline)-Containing Premixes; Opportunity for Hearing, 42 Fed. Reg. 56,264 (Oct. 21, 1977)

3 Pew Charitable Trusts, "Record-High Antibiotics Sales for Meat and Poultry Production," www.pewhealth.org/other-resource/record-high-antibiotic-sales-for-meat-and-poultry-production-85899449119, February 6, 2013, (accessed January 10, 2014); Food and Drug Administration, *2011 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM338170.pdf. Note: We are reporting here the statistic for all classes of antibiotics used in human medicine, and we have excluded ionophores. The commonly reported 80 percent statistic includes ionophores.

4 B.Marshall and S. Levy, "Food animals and antimicrobials: Impacts on human health," Clinical Microbiology Reviews 24(2011):718-733. DOI:10.1128/CMR.00002-11; D. Smith, et al., "Agricultural antibiotics and human health" PLOS Medicine 8(2005):0731-0735.DOI:10.1371/journal.pmed.0020232; K. Shea, "Antibiotic resistance: What is the impact of agricultural uses of antibiotics on children's health?" *Pediatrics* 112 (2003): 253-258; A. Matthew et al., "Antibiotic resistance in bacteria associated with food animals: A United States perspective of livestock production" Foodborne Pathogens and Disease 4(2007):115-133 DOI:10.1089/fpd.2006.0066.

5 H.R. 1150, 113th Congress, 1st Session (2013).

6 S. 1256, 113th Congress, 1st Session (2013).

7 J. Davies, "Microbes have the last word. a drastic re-evaluation of antimicrobial treatment is needed to overcome the threat of antibiotic-resistant bacteria," *EMBO Reports* 8 (2007): 616-621. S. Levy, "Confronting Multidrug Resistance," *JAMA* 269 (1993): 1840-1842. S. Levy and B. Marshall, "Antibacterial resistance worldwide: Causes, challenges, and responses," *Nature Medicine* 10 (2004): S122-S129.

8 Centers for Disease Control and Prevention, *Antibiotic Resistance Threats in the United States, 2013*, www.cdc.gov/drugresistance/threat-report-2013/ (accessed October 10, 2013). World Health Organization, *The evolving threat of antimicrobial resistance: Options for action*, 2013, http://whqlibdoc.who.int/publications/2012/9789241503181_eng.pdf (accessed October 10, 2013).

9 Centers for Disease Control and Prevention, *Antibiotic resistance threats in the United States, 2013*, at 11, www.cdc.gov/drugresistance/threat-report-2013/ (accessed October 10, 2013).

10 Centers for Disease Control and Prevention, *Antibiotic resistance threats in the United States, 2013*, at 24, www.cdc.gov/drugresistance/threat-report-2013/ (accessed October 10, 2013).

11 Pew Commission on Industrial Farm Animal Production, *Putting Meat on The Table: Industrial Farm Animal Production in America (2008),* http://www.ncifap.org/_images/PCIFAPFin.pdf (accessed January 8, 2014).

12 Frank Jones and Steven Ricke, "Observations on the history of the development of antimicrobials and their use in poultry feeds," *Poultry Science* 82 (2003): 613-617. NRC, 1999; Emborg et al., 2001; MacDonald and Wang, 2011 Dibner and Richards, 2005; Ferket, 2007; Graham et al., 2007; Dewey et al., 1999

13 Michael Apley et al., "Use estimates of in-feed antimicrobials in swine production in the United States," *Foodborne Pathogens and Disease* 9 (2012): 272-279. Margaret Mellon, Charles Benbrook, and Karen Lutz Benbrook, *Hogging it: Estimates of Antimicrobial Abuse in Livestock*, Union of Concerned Scientists, 2001. Jim Downing, "FDA: Food-animal antibiotic consumption dwarfs human medical use," *VIN News Service*, May 25, 2011, news.vin.com/VINNews.aspx?articleId=18659 (accessed October 10, 2013).

14 Ajit Sarmah, Michael Meyer, and Alistair Boxall, "A global perspective on the use, sales, exposure pathways, occurrence, fate and effects of veterinary antibiotics (VAs) in the environment," *Chemosphere* 65 (2006): 725-759. George G. Khachatourians, "Agricultural use of antibiotics and the evolution and transfer of antibiotic-resistant bacteria," *Canadian Medical Association Journal* 159 (1998): 1129-1136. Catherine E. Dewey et al., "Associations between off-label feed additives and farm size, veterinary consultant use, and animal age," *Preventive Veterinary Medicine* 31 (1997): 133-146.

15 Centers for Disease Control and Prevention, *Antibiotic resistance threats in the United States, 2013*, at 31, www.cdc.gov/drugresistance/threat-report-2013/ (accessed October 10, 2013).

16 Centers for Disease Control and Prevention, *Antibiotic Resistance Threats in the United States, 2013*, www.cdc.gov/drugresistance/threat-report-2013/ (accessed October 10, 2013).

17 Centers for Disease Control and Prevention, *Antibiotic Resistance Threats in the United States, 2013*, at 6, www.cdc.gov/drugresistance/threat-report-2013/ (accessed October 10, 2013).

18 Centers for Disease Control and Prevention, *Antibiotic Resistance Threats in the United States, 2013*, at 23, www.cdc.gov/drugresistance/threat-report-2013/ (accessed October 10, 2013).

19 The amounts of antibiotics sold or distributed are used as "a surrogate for nationwide antibacterial drug use in humans." Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, *Drug Use Review*, April 5, 2012, www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM319435.pdf (accessed November 5, 2013).

20 *See* World Health Organization, Critically Important Antimicrobials for Human Medicine, 3rd Revision, 2011, at 20, 24, http://apps.who.int/iris/bitstream/10665/77376/1/9789241504485_eng.pdf. According to the World Health Organization, one of the criteria for a "critically important" antibiotic is that it offers the *only* option or one of *very few* options available to treat serious human infectious disease. *Id.*, at 5.

21 According to the FDA, "critically important" drugs need to meet two criteria: they are (1)"used to treat enteric pathogens that cause food-borne illness" *and* (2) the "sole therapy or one of few alternatives to treat serious human disease, or an essential component . . . in the treatment of human disease." "Highly important" drugs meet one of those criteria. *See* Food and Drug Administration, Guidance for Industry No. 152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern,* 2003, at 29, www.fda.gov/downloads/AnimalVeterinary/ GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf (accessed October 10, 2013).

22 David Gilbert et al., *The Sanford Guide to Antimicrobial Therapy 2010* (Sperryville: Antimicrobial Therapy, Inc., 2010).

23 *See, e.g.,* Centers for Disease Control and Prevention, "CDC Grand Rounds: The Growing Threat of Multidrug-Resistant Gonorrhea," *Morbidity and Mortality Weekly Report*, February 15, 2013, www.cdc.gov/mmwr/preview/mmwrhtml/mm6206a3.htm (accessed November 5, 2013).

24 Table summarizes the most common uses of the highlighted antibiotics according to the reference David Gilbert et al., *The Sanford Guide to Antimicrobial Therapy 2010* (Sperryville: Antimicrobial Therapy, Inc., 2010).

25 M. Alekshun and S. Levy, "Molecular Mechanisms of Antibacterial Multidrug Resistance" *Cell* 128(2007):1037-1050. Stephanie Petrella et al., "Novel class A beta-lactamase Sed-1 from *Citrobacter sedlakii*: Genetic diversity of beta-lactamases within the *Citrobacter* genus," *Antimicrobial Agents and Chemotherapy* 45, No. 8(2001): 2287-2298.

26 Food and Drug Administration, *2011 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals*, 2011, www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM338170.pdf (accessed October 1, 2013).

27 Lance Price et al., "Elevated risk of carrying gentamicin-resistant *Escherichia coli* among U.S. poultry workers," *Environmental Health Perspectives* 115 (2007): 1738-1742. Jessica Rinsky et al., "Livestock-associated methicillin and multidrug resistant *Staphylococcus aureus* is present among industrial, not antibiotic-free livestock operation workers in North Carolina," *PLOS One* 8(2013): e67641, doi:10.1371/journal.pone.0067641. Tara Smith et al., "Methicillin-resistant *Staphylococcus aureus* (MRSA) strain ST398 is present in midwestern U.S. swine and swine workers," *PLOS One* 4(2009): e4258, doi:10.1371/journal.pone.0004258.

28 Khachatourians, *supra* note 10. Centers for Disease Control and Prevention, *supra* note 7. Y. Zhu et al., "Diverse and abundant antibiotic resistance genes in Chinese swine farms," *Proceedings of the National Academy of Sciences* 110 (2013): 3435-3440, doi: 10.1073/pnas.1222743110. A. Ling et al., Tetracycline resistance and class 1 integron genes associated with indoor and outdoor aerosols," *Environmental Science & Technology* 47 (2013): 4046-4052, doi: 10.1021/es400238g; L. Beuchat, "Vectors and conditions for preharvest contamination of fruits and vegetables with pathogens capable of causing enteric disease" *British Food Journal* 108(2006):38-53; A. Rule, "Food animal transport: A potential source of community exposures to health hazards from industrial farming (CAFOs), *Journal of Infection and Public Health*, 1(2008):33-39.

29 M. Davis et al., "An ecological perspective on U.S. industrial poultry production: The role of anthropogenic ecosystems on the emergence of drug-resistant bacteria from agricultural environments," *Current Opinion in Microbiology* 14 (2011): 244-250.

30 K. Shea, "Antibiotic resistance: What is the impact of agricultural uses of antibiotics on children's health?" *Pediatrics* 112 (2003): 253-258. E. Silbergeld et. al, "Industrial food animal production, antimicrobial resistance, and human health," *Annual Review of Public Health* 29 (2008): 151-169, doi:10.1146/annurev.publhealth.29.020907.090904. "J. Casey et al., "High-density livestock operations, crop field application of manure, and risk of community-associated methicillin-resistant Staphylococcus aureus infection in Pennsylvania," *JAMA Internal Medicine* 21(2013):1980-1990. Doi: 10.1001/jamainternmed.2013.10408

31 D. Love et al., "Dose imprecision and resistance: Free-choice medicated feeds in industrial food animal production in the United States" *Environmental Health Perspectives*, 119(2011):279-283. doi: 10.1289/ehp.1002625

32 R. Cantón and P. Ruiz-Garbajosa, "Co-resistance: An opportunity for the bacteria and resistance genes," *Current Opinion in Pharmacology* 11, No. 5 (2011): 477-485, doi: 10.1016/j.coph.2011.07.007. Adam C. Palmer and Roy Kishony, "Understanding, predicting and manipulating the genotypic evolution of antibiotic resistance," *Nature Reviews Genetics* 14 (2013): 243-248, doi: 10.1038/nrg3351

33 C. Knapp et al, "Evidence of increasing antibiotic resistance gene abundances in archived soils since 1940" *Environmental Science and Technology*, 44(2010):580-587; J. Chee et al., "Fate and transport of antibiotic residues and antibiotic resistance genes following land application of manure waste" Journal of Environmental Quality 38(2009):1086-1108. doi: 10.2134/jeq2008.0128

34 K. Jorgensen, et al., "Sublethal ciprofloxacin treatment leads to rapid development of high-level ciprofloxacin resistance during long-term experimental evolution of *Pseudomonas aeruginosa,*" *Antimicrobial Agents and Chemotherapy,*57 (2013): 4215-4221; M. Kohanski, et al., "Sub-lethal antibiotic treatment leads to multi-drug resistance bia radical-induced mutagenesis," *Molecular Cell* 37(2010):311-320; Gullberg et al., "Selection of resistant bacteria at very low antibiotic concentrations," *PLOS Pathogens* 7(2013):1-9 doi:10.1371/journal.ppat.1002158; M. Brewer et al., "Effects of subtherapeutic concentrations of antimicrobials on gene acquisition events in *Yersinia, Proteus, Shigella*, and *Salmonella* recipient organisms in isolated ligated intestinal loops of swine," *American Journal of Veterinary Research* 74(2013):1078-1083 doi: 10.2460/ajvr.74.8.1078; T. Looft et al., "In-feed antibiotic effects on the swine intestinal microbiome" *Proceedings of the National Academy of Sciences* 109(2012): 1691-1696 doi: 10.1073/pnas.1120238109. J. Roberts, et al, "Antibiotic resistance – What's dosing got to do with it?" *Critical Care Medicine* 36(2008):2433-2440 doi:10.1097/CCM.0b013e318180fe62.

35 M. Brewer et al., "Effects of subtherapeutic concentrations of antimicrobials on gene acquisition events in *Yersinia, Proteus, Shigella*, and *Salmonella* recipient organisms in isolated ligated intestinal loops of swine," *American Journal of Veterinary Research* 74(2013):1078-1083 doi: 10.2460/ajvr.74.8.1078; H. Ochman, et al., "Lateral gene transfer and the nature of bacterial innovation" *Nature* 405(2000): 299-304 doi:10.1038/35012500;

36 J. Martinez, "Antibiotics and antibiotics resistance genes in natural environments" Science 321:365-367 DOI: 10.1126/science.1159483; Y. Zhu, et al., "Diverse and abundant antibiotic resistance genes in Chinese swine farms," *Proceedings of the National Academy of Sciences* 110(2013): 3435-3440. doi/10.1073/pnas.1222743110;J. Chee et al., "Fate and transport of antibiotic residues and antibiotic resistance genes following land application of manure waste" *Journal of Environmental Quality* 38(2009):1086-1108. doi: 10.2134/jeq2008.0128; Kevin Forsberg et al., "The shared antibiotic resistome of soil bacteria and human pathogens," *Science* 337 (2012): 1107-1111; Lance Price et al., "Elevated risk of carrying gentamicin-resistant *Escherichia coli* among U.S. poultry workers," *Environmental Health Perspectives* 115 (2007): 1738-1742. M. Mulders et al., "Prevalence of livestock-associated MRSA in broiler flocks and risk factors for slaughterhouse personnel in the Netherlands," *Epidemiology and Infection* 138 (5): 743-755. H. Allen, et al., "Antibiotics in feed induce prophages in swine fecal microbiomes" mBio 2(2011): 1-9 doi/10.1128/mBio.00260-11; R. Aminov, "Horizontal gene exchange in environmental microbiota," *Frontiers in Microbiology* 2(2011):1-19 doi: 10.3389/fmicb.2011.00158

37 M. Roberts, "Tetracycline resistance determinants: mechanisms of action, regulation of expression, genetic mobility, and distribution," *FEMS Microbiology Reviews* 19(1996):1-24; K. Trzcinski, et al., "Expression of resistance to tetracyclines in strains of methicillin-resistant *Staphylococcus aureus,*" *Journal of Antimicrobial Chemotherapy* 45(2000):763-770. doi: 10.1093/jac/45.6.763; A. Pijpers et al., "In vitro activity of five tetracyclines and some other antimicrobial agents against four porcine respiratory tract pathogens" *Journal of Veterinary Pharmacology and Thereapeutic*s, 12(1989): 267-76.

38 C. Higgins, "Multiple molecular mechanisms for multidrug resistance transporters," *Nature* 446(2007):749-757 doi:10.1038/nature05630; H. Nikaido and J. Pages, "Broad specificity efflux pumps and their role in multidrug resistance of gram negative bacteria," *FEMS Microbiology Reviews* 36(2012):340-363. doi:10.1111/j.1574- 6976.2011.00290.x; L. Piddock, "Clinically relevant chromosomally encoded multidrug resistance efflux pumps in bacteria" *Clinical Microbiology Reviews* 19(2006):382-402. E. Toprak, et al., "Evolutionary paths to antibiotic resistance under dynamically sustained drug selection" *Nature Genetics* 44(2012):101-105. doi:10.1038/ng.1034

39 H. Nikaido, et al., "Broad-specificity efflux pumps and their role in multidrug resistance of Gram-negative bacteria" *FEMS Microbiology Reviews* 36(2012):340-363. DOI: 10.1111/j.1574-6976.2011.00290.x; Y. Takatsuka, et al., "Mechanism of recognition of compounds of diverse structures by the multidrug efflux pump AcrB of Escherichia coli" *Proceedings of the National Academy of Sciences* 107(2010):6559-65. doi:10.1073/pnas.1001460107.

40 R. Canton and P. Ruiz-Garbajosa, "Co-resistance: an opportunity for the bacteria and resistance genes" *Current Opinion in Pharmacology* 11(2011):477-485. doi: 10.1016/j.coph.2011.07.007; Y. Hsu et al., "Comparative study of class 1 integron, ampicillin, chloramphenicol, streptomycin, sulfamethoxazole, tetracycline (ACSSuT) and fluorquinolone resistance in various Salmonella serovars from humans and animals" *Comparative Immunology, Microbiology and Infectious Diseases* 36(2013):9-16. doi: 10.1093/jac/dkt28;

41 N. Woodford, Complete Nucleotide Sequences of Plasmids pEK204, pEK499, and pEK516, Encoding CTX-M Enzymes in Three Major *Escherichia coli* Lineages from the United Kingdom, All Belonging to the International O25:H4-ST131 Clone, *Antimicrobial Agents and Chemotherapy*. 53(2009):4472-4482.

42 *See, e.g.*, Food and Drug Administration, *2011 Retail Meat Report, National Antimicrobial Resistance Monitoring System*, 27 tbl.10 n.2, http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM334834.pdf.

43 FDA did not respond to the FOIA request until NRDC filed a lawsuit; subsequently a settlement was reached and documents were made available.

44 *Natural Resources Defense Council v. United States Food and Drug Administration*, 884 F.Supp.2d 127, 131-32 (S.D.N.Y. 2012) (hereinafter "*NRDC v. FDA*").

45 FDA also reviewed two antibiotics products that were not approved for use *in animal feed or water*, and determined that they are "high risk" under the 2003 guidelines discussed further below. The antibiotic products are approved for intramammary application to dairy cows (NADA 055-028), and for treatment use (NADA 055-060). They were not required to meet the 1973 safety requirements, which focused on the safety of antibiotic feed additives. FDA examined the topical antibiotic because it was approved for preventive use, but it is not clear why FDA reviewed the antibiotic product approved for treatment. It remains unclear if and how safety for human health was established for these two antibiotic products; Food and Drug Administration, Microbiologist's Review of NADA 055-028, Vol. III, FDA007723-7739; Food and Drug Administration, Microbiologist's Review of NADA 055-060, Vol. II, FDA004531-4537.

46 *See* example of credentials listed in the individual reviews, Food and Drug Administration, Microbiologist's Review of NADA 008-622, Vol. III, FDA007076.

47 Senate and House Conference Committee on the amendment of the Senate to H.R. 2330, "Making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2002, and for other purposes," 107th Congress, 1st session, November 9, 2001, H.R. Rep. 107-275, at 82 (2001), www.gpo.gov/fdsys/pkg/CRPT-107hrpt275/pdf/CRPT-107hrpt275.pdf (accessed October 16, 2013); *see, e.g.*, Letter from FDA to Sponsor of NADA 046-666, May 26, 2004, Vol. III: FDA007515.

48 Food and Drug Administration, Microbiologist's Review of NADA 065-123, Tetracycline Soluble Powder, Vol. III, FDA004566-67.

49 Appendix I, Column 4, shows which antibiotics failed to meet the 1973 criteria.

50 *NRDC v. FDA*, 884 F.Supp.2d at 133.

51 Three antibiotic products (NADA 065-496, 055-020, and 008-622) are additives approved for administration to animals for fewer than 14 days and the 1973 criteria may not apply. "In the past, FDA has referred to ''subtherapeutic'' uses at various times to include: (1) 'Increased rate of gain, disease prevention, etc.' (Ref. 7); (2) 'any use of an antibacterial drug continuously in feed for longer than 14 days' (Ref. 23); and (3) 'lower levels than therapeutic levels needed to cure disease.' (Refs. 1 and 2)." Withdrawal of NOOH; Penicillin and Tetracycline Used in Animal Feed, 76 Fed. Reg. 79697, 79700 (Dec. 22, 2011). See Appendix I, Column 4 and 8, show which antibiotics failed to meet the 1973 criteria and if the 1973 criteria were applicable.

52 *See* Food and Drug Administration, Microbiologist's Review of NADA 008-804, Vol. I, FDA002097, FDA002114. The approved NADA covers several versions of the same feed additive, a Terramycin Animal Mix.

53 See Appendix I, column 5.

54 Food and Drug Administration, Guidance for Industry No. 152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern,* 2003, at 23-25 www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf .

55 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360b(d)(1)(B).

56 *Id.*, § 360b(e)(1)(B).

57 See pages following documents cited in Appendix III.

58 *See* Food and Drug Administration, Approved Animal Drug Products Online (Green Book), http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm) (last accessed January 15, 2014). The two drugs that were voluntarily discontinued or withdrawn are Rainbrook Broiler Premix No. 1 (NADA No. 49-462) and Terramycin Premix (NADA No. 103-758). Food and Drug Administration, Microbiology Food Safety Review of NADA 49-462, at 6-7, Vol. II, FDA004486-87; Food and Drug Administration, Microbial Food Safety Review of NADA 103-758, at 1-2, Vol. III, FDA004838-39. Please note that the FDA database at AnimalDrugs@FDA (http://www.accessdata.fda.gov/scripts/animaldrugsatfda/) lists NADA 103-758 as voluntarily withdrawn; however, the official "Green Book" does not.

59 *NRDC v. FDA*, 884 F.Supp.2d at 133 (citing 42 Fed.Reg. 43,772, 43,774 (Aug. 30, 1977)).

60 Food and Drug Administration, Guidance for Industry No. 152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern,* 2003, www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf (accessed October 10, 2013) (hereinafter, "Guidance #152").

61 Food and Drug Administration, Microbiologist's Review of NADA 134-938 "Part I: Summary of Findings," Vol. III, FDA004872. ii. *Id.*

62 *Id.*

63 *See* Appendix III, NADA 138-934, Excerpt from FDA letter sent to sponsor.

64 *See* Approved usages for NADA 134-938, Vol. III, FDA004847-48; 21 C.F.R. § 558.145.

65 *See* Food and Drug Administration, Microbiologist's Review of NADA 134-938, at 24-25, Vol. III, FDA004876-77.

66 FDA's current statements on the issue of preventive claims, in non-binding policy documents such as Guidance #213, explain that FDA does not consider prevention uses to be subtherapeutic anymore, contradicting its own binding regulations, 21 C.F.R. § 558.15, despite the fact that the claims may overlap in the use allowed.

67 *See* Approved usages for NADA 134-938, Vol. III, FDA004847-48; 21 C.F.R. § 558.145.

68 *See* Appendix III, NADA 138-934, Excerpt from FDA's summary of the sponsor's response; *see also* Food and Drug Administration documents concerning NADA 134-938, Vol. III, FDA004846-4885.

69 *See* Food and Drug Administration documents concerning NADA 134-938, Vol. III, FDA004846-4885

70 *See* Appendix II.

71 "From CVM to the sponsor… The letter indicates that considerable concern is being expressed by public health officials and representatives of the human health care community regarding the emergence of antimicrobial resistance. Attention is being drawn to the use of antimicrobials in animals as a source of the increasing resistance… The sponsor is asked to voluntarily withdraw their product." Food and Drug Administration, Microbiologist's Review of NADA 046-666, Part I: Review of Administrative Record, Vol. II, FDA003974.

72 "From CVM to the sponsor… The letter also states that the products subject to this NADA were determined to be effective for increasing rate of growth and improving feed efficiency under the DESI review, the products failed to meet antimicrobial resistance criteria established under 21 CFR 558.15 and as a result…were proposed for withdrawal via an NOOH published in 1977." Food and Drug Administration, Microbiologist's Review of NADA 046-666, Part I: Review of Administrative Record, Vol. II, FDA003974.

73 "It is interesting to note that although the sponsor makes the following statement in the body of their report, 'Among the non-infected groups, there were significantly more ampicillin, chloramphenicol, nitrofurantoin and kanamycin resistant *E. coli* in the treated group than in the control group,' this does not appear in the conclusions section of their report." Food and Drug Administration, Microbiologist's Review of NADA 046-666, Review of Data Pertaining to 558.15, Vol. II, FDA004019; *see* Letter from FDA to Sponsor of NADA 046-666, May 26, 2004, Vol. III, FDA007515 (noting that CVM concluded that "there were still questions about the observed increases in resistant *Salmonella* and *E. coli")*.

74 "From sponsor: 'We are of course, aware of the renewed controversy over the use of certain antibacterials in animals; however, we continue to believe that when their safety is called into question, new animal drug approvals should only be withdrawn when there is sound scientific evidence for so doing. Mere speculation and theory should not be a basis for withdrawal of approval.'" Food and Drug Administration, Microbiologist's Review of NADA 046-666, Part I: Review of Administrative Record, Vol. II, FDA003974.

75 *See* Food and Drug Administration documents concerning NADA 046-666, Vol. II, FDA003946-4075.

76 *See* Appendix III, NADA 046-666, Excerpt from FDA letter sent to sponsor.

77 *Id.*

78 "Product inserts – Penicillin 100," Zoetis, last modified 2013, https://online.zoetis.com/US/EN/contact/product_information/Pages/ProductInserts.aspx, accessed November 26, 2013;"Material Safety Data Sheet," Zoetis, https://online.zoetis.com/US/EN/MSDS_PI/PI/Penicillin_100.pdf, accessed November 25, 2013;"PALS feed additives and medication products catalog" PALS USA, http://palsusa.com/files/PALSMedCatalog.pdf, last accessed November 21, 2013.

79 *NRDC v. FDA*, 884 F.Supp.2d at 132-33.

80 Carol Cogliani, Herman Goossens, and Christina Greko, *Restricting Antimicrobial Use in Food Animals: Lessons from Europe*, Microbe Magazine (June 2011), www.microbemagazine.org/index.php?option=com_content&view=article&id=3458:restricting-antimicrobial-use-in-food-animals-lessons-from-europe&catid=752&Itemid=995.

81 Antibiotic Resistance and the Use of Antibiotics in Animal Agriculture: Hearing Before the House Committee on Energy and Commerce, Subcommittee on Health, 111th Congress, (July 14, 2010) (statement of Per Henriksen, D.V.M., Ph.D., Head, Division for Chemical Food Safety, Animal Welfare, and Veterinary Medicinal Products, Danish Veterinary and Food Administration), http://democrats.energycommerce.house.gov/sites/default/files/documents/Testimony-Henriksen-HE-Antibiotic-Resistance-Animal-Agriculture-2010-7-14.pdf.

82 *NRDC v. FDA*, 884 F.Supp.2d at 133.

83 *Id.* at 133-34.

84 *Id. generally*; *Natural Resources Defense Council v. U.S. Food and Drug Administration*, 872 F.Supp.2d 318 (S.D.N.Y. 2012).

85 Guidance #152.

86 Government Accountability Office, Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals 24 (September 2011), http://www.gao.gov/assets/330/323090.pdf; Food and Drug Administration, Guidance for Industry No. 152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern* (October 23, 2003), www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf .

87 Food and Drug Administration, Guidance for Industry No. 213 , *New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209 (December 2013),* http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm299624.pdf (hereinafter, "Guidance #213").

88 Food and Drug Administration, Guidance for Industry No. 209, *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* 21 n.5 (*April 13* 2012), http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm216936.pdf.

89 Government Accountability Office, Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals 28 (September 2011), http://www.gao.gov/assets/330/323090.pdf.

90 21 C.F.R. § 558.15.

Method and Appendices endnotes

i For all of the antibiotic feed additives listed in this appendix, FDA did not have sufficient data to conduct a thorough risk assessment. However, for 18 antibiotic feed additives, it had sufficient information to carry out an abbreviated risk assessment. Even for these 18 additives, the assessment was more thorough for some additives than for others. "High risk" indicates that FDA scientists conducted a basic risk assessment. "High risk**" indicates that FDA conducted a more detailed assessment considering release, exposure, and consequence. See the following for example: Food and Drug Administration, Assessment of the Administrative Record using Guidance for Industry #152 – NADA 091-668, Vol. III, FDA004724-4730. For the other 12 additives, FDA concluded that it simply did not have sufficient information to be able to make any determination about risk. These additives are thus not shown to be safe.

ii *Two antibiotic products (NADA 055-060 and NADA 055-028) are not included in the 30 antibiotic feed additives discussed in the main text. #Three antibiotic products (NADA 065-496, 055-020, and 008-622) are additives approved for administration to animals for fewer than 14 days as indicated in Animal Drugs @ FDA database and the 1973 criteria may not be applicable.. (See main text for further information). Animal Drugs @ FDA database, http://www.accessdata.fda.gov/scripts/animaldrugsatfda/

iii Please note that the FDA database at AnimalDrugs@FDA (http://www.accessdata.fda.gov/scripts/animaldrugsatfda/) lists NADA 103-758 as voluntarily withdrawn; however, the official "Green Book" does not.

iv Note that the same sponsor is associated with NADAs 046-666, 035-688, 039-077, and 091-668. The sponsor sent only one letter in response to FDA's concerns and comments on all four NADAs.

Natural Resources Defense Council
40 West 20th Street
New York, NY 10011
212 727-2700
Fax 212 727-1773

Beijing

Chicago

Los Angeles

Bozeman

San Francisco

Washington, D.C.

www.nrdc.org

www.nrdc.org/policy
www.facebook.com/nrdc.org
www.twitter.com/nrdc

Printed on recycled paper

Attachment 27

» Print

Drug critic slams FDA over antibiotic oversight in meat production

Mon, Jan 27 2014

By P.J. Huffstutter and Brian Grow

(Reuters) - The United States Food and Drug Administration allowed 18 animal drugs to stay on the market even after an agency review found the drugs posed a "high risk" of exposing humans to antibiotic-resistant bacteria through food supply, according to a study released Monday by the Natural Resources Defense Council.

The study by the NRDC, a non-governmental group that criticizes the widespread use of drugs in the meat industry, is the latest salvo in the national debate over the long-standing practice of antibiotic use in meat production. Agribusinesses say animal drugs help increase production and keep prices low for U.S. consumers, while consumer advocates and some scientists raise concerns over antibiotic-resistant bacteria.

The FDA stirred the debate late last year when it unveiled guidelines for drug makers and agricultural companies to voluntarily phase out antibiotic use as a growth enhancer in livestock. The agency said those guidelines were an effort to stem the surge in human resistance to certain antibiotics.

But the NRDC's study found the FDA took no action to remove 30 antibiotic-based livestock feed products from the market even after federal investigators determined many of those antibiotics fell short of current regulatory standards for protecting human health.

NRDC studied a review conducted by the FDA from 2001 to 2010 that focused on 30 penicillin and tetracycline-based antibiotic feed additives. The drugs had been approved by regulators to be used specifically for growth promotion of livestock and poultry - essentially to produce more meat to sell.

The FDA, in a statement, said it began a review of older, approved penicillin and tetracycline products in 2001, and issued letters to companies who made the products asking for additional safety data.

"Based on its review of this and other information, the Agency chose to employ a strategy that would more broadly address the concerns about the production use of medically important antimicrobials in food-producing animals," the FDA said.

Some academics specializing in antibiotic resistance criticized the NRDC's study, saying that the findings do not reflect current regulatory standards because some of the drugs have been withdrawn from the market.

They also say that the study assessed FDA safety guidelines that have been replaced with more stringent standards.

Dr. Randall Singer, associate professor of epidemiology at the University of Minnesota, told Reuters that drug makers and the U.S. livestock industry are phasing out antibiotics used principally for growth promotion.

"We have been telling (both of) them for years to be prepared for the elimination of growth promotion and feed efficiency labeling because you cannot make that change overnight," said Singer, who reviewed the NRDC report for Reuters.

The NRDC, which reviewed more than 3,000 pages of documents through a federal Freedom of Information Act request, said it found evidence to suggest nine of the drugs are still on the market and used by livestock producers. Reuters was not able to independently verify that detail immediately.

One of the drugs still on the market is animal health company Zoetis Inc's Penicillin G Procaine 50/100, which is fed to poultry in part to aid in weight gain.

The NRDC says the FDA twice laid out its concerns to that drug maker that the product failed to meet safety regulations. The unnamed original sponsor of the drug apparently disputed the regulators' findings, according to excerpts from a 1997 letter sent to the FDA and included in documents obtained by the NRDC.

A spokeswoman for Zoetis, a unit of Pfizer Inc that owns the drug today, said the company already is working to phase out use of the drug for growth promotion as part of the new FDA guidelines and is planning to relabel the drug for more limited purposes.

Once companies remove farm-production uses of their antibiotics from drug labels, it would become illegal for those drugs to be used for those purposes, Deputy FDA Commissioner Michael Taylor told reporters recently. Although the program is meant to be voluntary, Taylor said the FDA would be able to take regulatory action against companies that fail to comply.

In its statement on Monday, the FDA said it is "confident that its current strategy to protect the effectiveness of medically important antimicrobials, including penicillins and tetracyclines, is the most efficient and effective way to change the use of these products in animal agriculture."

NRDC attorney Avinash Kar, one of the study's authors, said the group's findings raise questions about whether regulators will be effective in enforcing the new guidelines.

"The FDA's failure to act on its own findings about the 30 reviewed antibiotic feed additives is part of a larger pattern of delay and inaction in tackling livestock drug use that goes back four decades," Kar told Reuters.

(Reporting By P.J. Huffstutter in Chicago and Brian Grow in Atlanta; Editing by David Greising, Amanda Kwan and Kenneth Maxwell)

Attachment 28

NRDC REPORT

APRIL 2014
R:14-03-A

Generally Recognized as Secret:
Chemicals Added to Food in the United States

AUTHORS:

Tom Neltner, J.D.
Maricel Maffini, Ph.D.
Natural Resources Defense Council

EXECUTIVE SUMMARY

When President Eisenhower signed the Food Additives Amendment of 1958, he established a regulatory program intended to restore public confidence that chemicals[a] added to foods are safe. In the intervening 56 years, the basic structure of the law has changed little. However, the regulatory programs the U.S. Food and Drug Administration (FDA) established to implement the law have fallen behind over time as the agency strived to keep up with the explosion in the number and variety of chemicals in food, and to manage its huge workload with limited resources.

The 1958 law exempted from the formal, extended FDA approval process common food ingredients like vinegar and vegetable oil that are "generally recognized as safe" (GRAS). It may have appeared reasonable at the time, but that exemption has been stretched into a loophole that has swallowed the law. The exemption allows manufacturers to make safety determinations that the uses of their newest chemicals in food are safe without notifying the FDA. The agency's attempts to limit these undisclosed GRAS determinations by asking industry to voluntarily inform the FDA about their chemicals are insufficient to ensure the safety of our food in today's global marketplace with a complex food supply. Furthermore, no other developed country in the world has a system like GRAS to provide oversight of food ingredients.

Because of the apparent frequency with which companies make GRAS safety determinations without telling the FDA, NRDC undertook a study to better understand companies' rationale for not participating in the agency's volutnary notification program. First, we built a list of companies and the chemicals they market. Then we reviewed public records, company websites, and trade journals to identify additives that appear to be marketed in the U.S. pursuant to an undisclosed GRAS determination, i.e. without notification to the FDA.

All told, we were able to identify 275 chemicals[a] from 56 companies that appear to be marketed for use in food based on undisclosed GRAS safety determinations. This is likely the tip of the iceberg—we previously published in an industry journal an estimate that there have been 1,000 such secret GRAS determinations.[1] For each chemical we identified in this study, we did not find evidence that FDA had cleared them.

In addition, using the Freedom of Information Act (FOIA), we obtained from the FDA copies of communications between the agency and companies who voluntarily sought agency review of their GRAS determinations. We found this glimpse into the review process shows that often the agency has had serious concerns about the safety of certain chemicals, and that companies sometimes make safety decisions with little understanding of the law or the science. As discussed later, companies found their chemicals safe for use in food despite potentially serious allergic reactions, interactions with common drugs, or proposed uses much greater than company-established safe doses.

On those occasions when the FDA is asked to review a GRAS determination, the agency rejects or triggers withdrawal of about one in five notices. Moreover, the public has even less information about the many substances with GRAS determinations that are never submitted to the agency in the first place—and which may pose a much greater danger. It is often virtually impossible for the public to find out about the safety—or in many cases even the existence—of these chemicals in our food.

"Generally Recognized as SECRET" rather than "Generally Recognized as SAFE" is a better name for the GRAS loophole that has allowed manufacturers to sanction the use of hundreds of chemicals in food that Americans eat every day.

a We use the term "chemicals" to apply to the products sold by additive manufacturers. They may be individual substances or mixtures of substances. They are sometimes referred to as substances, additives, or ingredients, which, in reality, are all chemicals or mixtures of them. They may be extracted from natural products or synthesized from other chemicals.

"We cannot require anything, as this is a voluntary program and we don't want to frighten anyone away. Having said that, we would typical [sic] tell any notifier that their submission would have to address the total dietary exposure from new and current uses, [h]ow else could you conclude that the uses were safe, without a notion of what total exposure is[?]"[2]

FDA reviewer of GRAS determination submitted by manufacturer

NRDC believes that "Generally Recognized as SECRET" rather than "Generally Recognized as SAFE" is a better name for the GRAS loophole. A chemical additive cannot be "generally recognized as safe" if its identity, chemical composition, and safety determination are not publicly disclosed. If the FDA does not know the identity of these chemicals and does not have documentation showing that they are safe to use in food, it cannot do its job.

In an increasingly global marketplace where many additives and foods are imported into the United States, this loophole presents an unsettling situation that undermines public confidence in the safety of food and calls into question whether the FDA is performing its duty to protect public health.

The problem is rooted in a law adopted in 1958 when Dwight Eisenhower was president and Elvis was drafted. It is time for the FDA and Congress to fix the problems. In the meantime, consumers need to demand that their grocery stores and their favorite brands sell only those food products with ingredients that the FDA has found to be safe.

GRAS: HOW THE LOOPHOLE SWALLOWED THE LAW

Over the last five years, there have been many news stories about unsafe foods that have sickened people. There have been a few reports of acute health problems related to chemicals added to foods, such as energy drinks containing a mixture of caffeine and alcohol, or rice with excessive amounts of the vitamin niacin. But chemicals added to food are more likely to be associated with health problems that may appear after years of frequent food and beverage consumption. These problems are often chronic in nature. The FDA is unlikely to detect an adverse health effect (short of immediate serious injury) unless companies notify it about the chemical and its use in food.

That is why Congress required that a chemical's intentional use in food be determined to be safe prior to its entering the marketplace.[3] In 1958 President Eisenhower signed the Food Additives Amendment to the Federal Food Drug and Cosmetic Act to address these concerns.[4] The law presumed that a chemical intentionally added to food was potentially unsafe and required that no chemical be used without a "reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."[5] Congress required food companies to file a "food additive petition" as the primary means by which to get an FDA approval of a chemical's use in food. If the agency did propose to approve the chemical, it would inform the public and request comments before adopting a regulation allowing the use.[6] The system was designed at a time when an estimated 800 chemical additives were in use, far fewer than the more than 10,000 allowed today.[7,8]

"The next day, [notifier] called and asked whether [notifier] would have an option to withdraw the notice rather than receive a letter that the notice did not provide a basis for a GRAS determination. I replied that this was an option. On September 4, [notifier] asked whether [notifier] could still sell its [name] product if it withdrew its GRAS notice. Consistent with my response to her earlier question about marketing [name], I said yes."[9]

FDA officer summarizing telephone conversations with manufacturer regarding its GRAS notice review

Determining that a chemical's use in food is and remains safe typically involves significant professional judgment. Rarely are these decisions clear cut; there is no bright line. So who decides is critical. Congress concluded that the FDA would make all safety decisions, except in the most obvious situations in which a chemical's use in food was "generally recognized as safe." This is known as the GRAS exemption. Examples include such common food ingredients as oil and vinegar. When a chemical's use was determined to be GRAS, the FDA did not need to adopt a regulation specifically allowing its use, and the formal public notice and comment rulemaking process was not required.[10] In other words, the

chemical didn't need premarket approval by the agency, and manufacturers could use it without delay. To qualify as GRAS, a chemical's safety had to be generally recognized by knowledgeable scientists, as borne out by published safety studies unless commonly and safely used before 1958.[11]

However, the FDA and the food industry interpreted the law as allowing manufacturers to determine that a chemical's use in food was safe without notifying the agency.[12] As a result, the identity of the chemical and the foods in which it was being used could be unknown to the public and the agency. Since 1958, an estimated 1,000 chemicals have been determined as GRAS by manufacturers and have been used in food without any approval or review by the FDA.[13] The exemption has become a loophole that has swallowed the law.

THE FDA'S ATTEMPTS TO LIMIT UNDISCLOSED INDUSTRY SAFETY DECISIONS

Recognizing the problem of undisclosed safety decisions, the FDA adopted regulations in 1972 inviting manufacturers to voluntarily submit "GRAS affirmation petitions" in a rulemaking process that was similar to the one for food additive petitions, but without statutory deadlines for action.[14] Companies sought FDA's approval, it appears, because their product would be more widely accepted by food manufacturers.

By the early 1990s, confronted with limited resources and an increasingly complicated and time-consuming formal rulemaking process, the FDA faced an overwhelming backlog of unresolved reviews.[15] In response, the agency proposed a rule in 1997 to replace the 1972 GRAS petition process with a less formal review process that did not involve adopting regulations for specific chemicals.[16] The next year, the FDA began accepting voluntary notifications from the companies that summarized the safety evidence and issuing decision letters.[17] In some cases, these decision letters are often cited by the companies as evidence of FDA clearance, although the agency maintains that the letters are informal and do not constitute approval. This process, however, largely cuts the public and outside experts out of meaningful participation in decision making. The proposed rule has never been finalized despite its wide use by industry and the FDA.[18] Since 2000, almost all new chemicals have passed through the loophole rather than being subjected to the food additive petition process established by Congress in 1958.

In 2010, the Government Accountability Office (GAO), the nonpartisan investigative arm of Congress, scrutinized the agency's GRAS program and found serious shortcomings. It concluded that "FDA's oversight process does not help ensure the safety of all new GRAS determinations" and that "FDA is not systematically ensuring the continued safety of current GRAS substances."[19]

Given these concerns, NRDC sought to identify examples of chemicals marketed pursuant to undisclosed GRAS safety determinations, procure such safety determinations from companies, and examine why companies choose to forgo even the voluntary FDA notification process.

CLAIMING GENERAL RECOGNITION WHILE AVOIDING DISCLOSURE

As mentioned above, some 1,000 chemicals have been determined by manufacturers to be safe for use in food without FDA review or approval. Some of them, like artificial *trans* fat, were self-certified by industry as safe ingredients decades ago and are well known.

NRDC's investigation focused on newer, less known chemicals marketed as GRAS for use in food in the United States since 1997. We looked at situations in which:

- the manufacturer opted to rely on an undisclosed GRAS determination, without using the FDA's voluntary notification process;
- the manufacturer notified the FDA, and the agency subsequently rejected the company's GRAS notice;
- the manufacturer notified the FDA but subsequently withdrew its notice from FDA review. (We will discuss the problems with withdrawal of notices later.)

Our investigation began with a list of companies and chemicals from three sources:

- the little-known (outside of the food additives industry) web-based "GRAS Self-Determination Inventory Database," compiled by a consulting firm that makes GRAS safety determinations for industry;[20]
- consultants who provided company names based on their experience at food industry trade shows;
- withdrawn or rejected notices in FDA's GRAS Notice Inventory.[21]

Overall, we identified 398 chemicals marketed by 163 companies that appear to be marketed in the U.S. based on GRAS determinations not reviewed by FDA.[b]

For each chemical, we sought a copy of the written documentation of the GRAS safety determination required by FDA's regulations (21 CFR §170.30), which companies must have completed before marketing a product as GRAS. This documentation must provide the chemical composition of the substance, describe how it is made, estimate how much people are likely to consume (exposure), and describe what is known about the chemical's potential hazards. Unless a chemical was commonly and safely used before 1958, the key studies evaluating the hazards ordinarily must be published, preferably in a peer review journal but the FDA does not exclude publication on a company's website. While identifying a key study is helpful, it is not a substitute for providing the full safety determination.

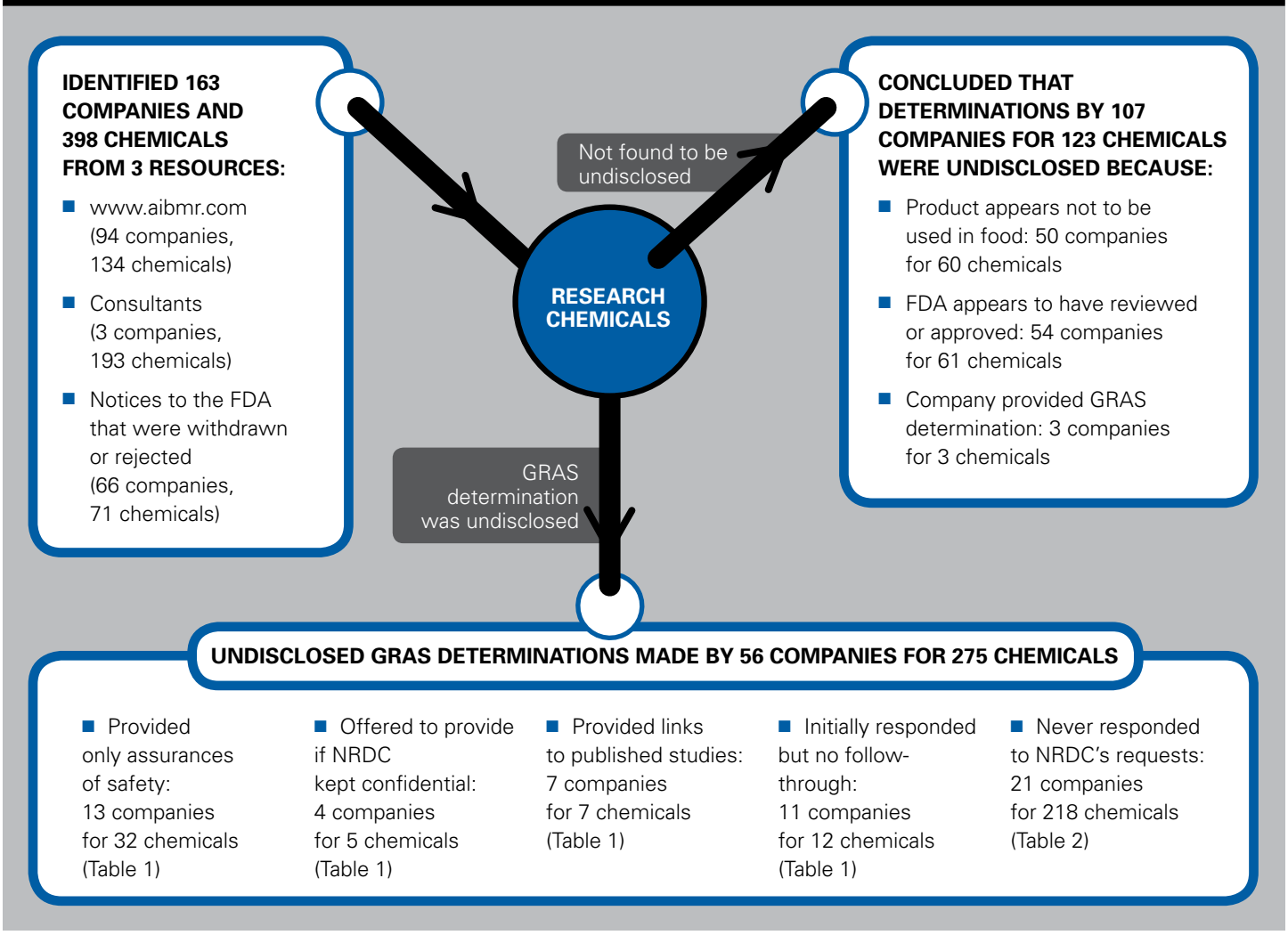
Where a company appeared to be marketing a chemical for use in the United States as GRAS without final FDA review, NRDC contacted the company to request a copy of the undisclosed safety determination. If the company declined or did not respond to our request, we classified the GRAS determination as "undisclosed". Also, if the company did not provide us with a revised GRAS determination that addressed the FDA's concerns after the agency rejected the company's notice, or if the company withdrew its notice before the agency made a final decision, we considered the GRAS determination to be undisclosed.

"GENERALLY RECOGNIZED AS SECRET"

All told, 56 companies appear to rely on undisclosed GRAS safety determinations for 275 chemicals (Figure 1):

- 35 companies selling 57 chemicals responded to our inquiries, but did not provide their GRAS safety determination (Table 1).
- 21 companies selling 218 chemicals did not respond to our repeated inquiries (Table 2).

Figure 1: Process to Identify and Evaluate Companies and Chemicals



b Where chemicals had similar names but different manufacturers, we treated them as separate chemicals.

Table 1: Companies with undisclosed GRAS determinations that responded to NRDC						
Company	**Country**	**No. of Chemicals**	**Declined Requests**	**Only if Confidential**	**Only Gave Studies**	**No Follow-up**
Albion	USA	2	Yes	Yes		
Aloecorp	Korea	1				Yes
BASF	Germany	2				Yes
BioCell Technology	USA	1	Yes			
Bioriginal	Canada	1	Yes	Yes	Yes	
ChromaDex	USA	1				Yes
Cyvex Nutrition	USA	3	Yes			
DSM	Netherlands	8	Yes			
Embria Health Sciences	USA	1	Yes			
ESM Technologies	USA	1	Yes		Yes	
Frutarom Health	Israel	1				Yes
Genosa	Spain	1	Yes			
GTC Nutrition	USA	1				Yes
HG&H Pharmaceuticals (Pty) Ltd.	South Africa	1	Yes			
House Wellness Foods	Japan	1	Yes			
InterHealth Nutraceuticals	USA	4	Yes			
Ixoreal Biomed	India	1				Yes
Jungbunzlauer	Switzerland	1	Yes			
Kaneka	Japan	1	Yes		Yes	
Kemin	USA	1	Yes			
Lonza	Switzerland	1				Yes
Merck Eprova AG	Germany	1	Yes		Yes	
NattoPharma	Norway	1				Yes
NuLiv Science	USA	1	Yes		Yes	
NutraGenesis	USA	4	Yes			
P.L. Thomas	USA	1				Yes
PhenoFarm	Italy	1				Yes
RIBUS	USA	1	Yes			
Sabinsa Corporation	USA	5	Yes			
SoluBlend Technologies	USA	1	Yes	Yes		
Stepan	Netherlands	1	Yes			
Trace Minerals Research	USA	1	Yes		Yes	
TSI Health Sciences	USA	1	Yes	Yes		
Unibar	USA	1				Yes
Verdure Sciences Trim	USA	1	Yes		Yes	
Totals	**35 companies**	**57**	**24**	**4**	**7**	**11**

The 35 companies that responded but did not provide us with their GRAS determinations fit into the following four categories:

- 13 companies provided us only with assurances that their chemicals were safe and complied with the law.
- 4 companies were willing to share the documentation only if NRDC signed a confidentiality agreement, which we declined to do.
- 7 companies declined to provide the GRAS determination but identified a published toxicology study that supported their analysis without providing the additional information such as exposure calculations and product composition needed to evaluate the safety.
- 11 companies acknowledged the inquiry but did not follow through.

The remaining 107 companies selling 123 chemicals fell into three general categories:

- 50 companies did not appear to market their chemicals for use in food in the United States.[c]
- 54 companies that withdrew notices to the FDA later submitted revised notices and received a final review by the agency confirming product safety.
- 3 companies provided NRDC with a copy of their GRAS determination without requiring confidentiality.

Figure 2 summarizes our findings. Of the 163 companies we reviewed, 56, or 34 percent, appear to rely on undisclosed GRAS determinations.

UNDISCLOSED SAFETY DETERMINATIONS: NOT JUST U.S. COMPANIES

As stated earlier, no other developed country in the world has a system like GRAS for food ingredients.[22] On the basis of each company's website and communications, NRDC identified the home country of the 56 companies with undisclosed GRAS determinations. See Tables 1 and 2. Figure 3 provides the results by region.

Fifty-six percent of the companies are from the United States, and 44 percent are based outside the country. This distribution is similar to what one might see at a typical food expo.

WHY DID COMPANIES FORGO FDA REVIEW?

About 20 companies provided explanations for why they decided not to submit a voluntary notification to the FDA. These can be distilled into the following categories:

- **Concerns about too much FDA transparency.** The most common concern was the FDA's routine posting of GRAS safety determinations to its website. These companies said they were worried that easy access to information about product composition and the manufacturing process would enable competitors to develop identical or similar chemicals and would simplify the competition's own GRAS determinations.
- **Concerns about FDA delays.** Several companies claimed they did not want to wait for the FDA to make a decision, even though the agency explicitly allows the use and marketing of a chemical while a review is under way.

> *"In other words, if a panel of experts reviews data that are not publicly available and subsequently renders an opinion regarding safety, even if the experts are well-recognized, the opinion does not meet the general recognition of safety for GRAS ingredients because the data were not publicly available."*[23]
>
> FDA reviewer of GRAS notice

c Either these chemicals appear to be used only in dietary supplements and not food, or we could not find an active website for the company or the chemical, or the chemicals appear to be marketed only overseas.

- **Desire to keep investment low.** Submitting a GRAS determination to FDA typically means additional work whether by company employees or a consultant doing the analysis. The agency asks many questions that must be answered. Often there are meetings with the agency. We found that almost all of the chemicals NRDC reviewed were also ingredients in dietary supplements and served no essential purpose in food other than to attract consumers' attention. Several companies indicated that a GRAS determination sometimes is done in connection with a test of the food market for a chemical previously used only as a dietary supplement ingredient, thus minimizing the investment in an unproven market by opting out of the FDA review process.
- **Wish to avoid new dietary ingredient review:** The Dietary Supplement Health and Education Act of 1994 (DSHEA) requires manufacturers to notify FDA about dietary ingredients that either were not on the market before 1994 or whose use in food is not GRAS. Several dietary supplement manufacturers appear to be making a GRAS determination to avoid having to notify the FDA under both DSHEA and the Food Additives Amendment of 1958.
- **Misunderstanding of the law:** Some companies apparently did not understand the requirements for a GRAS determination. It appears that they did not realize that the determination must be written, that safety information must be drawn from published scientific studies, or that "generally recognized as safe" means more than obtaining the opinion an employee or consultant. Others apparently believed that an independent panel of experts was required even though the FDA states that no panel is needed.[24] Finally, some companies appeared not to understand the difference between an efficacy study, which determines whether a chemical is effective in addressing a health problem, and a toxicology study, which evaluates whether a chemical may cause harm. The scope of most efficacy studies falls far short of an adequate toxicology study.

Figure 2: Undisclosed vs. Resolved GRAS Determinations

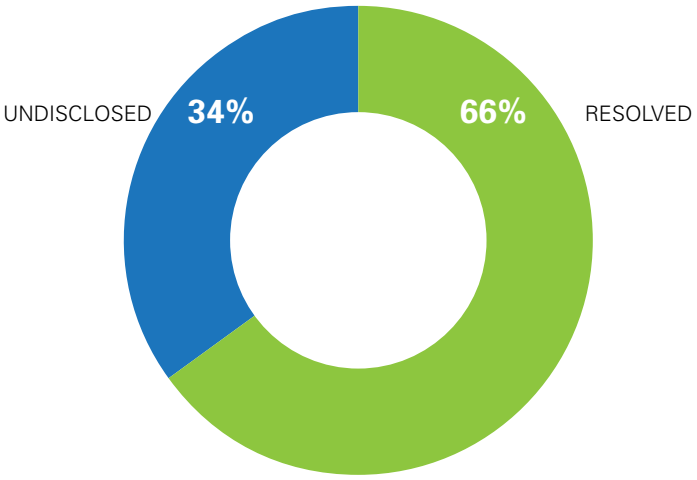
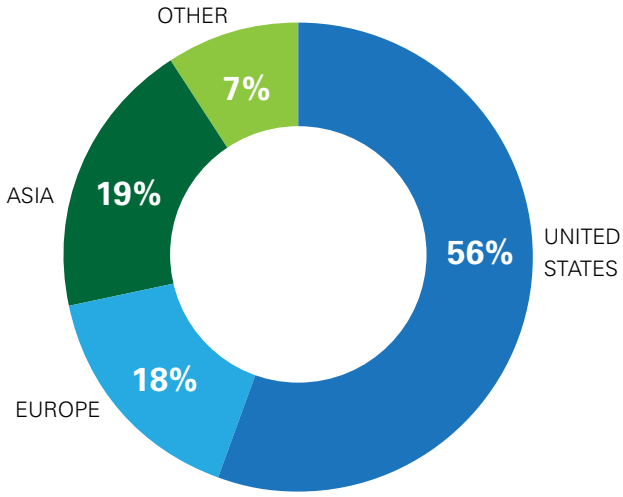


Figure 3: Undisclosed GRAS Determinations by Company's Region



FDA REVIEWS OF NOTICES REVEALED TROUBLING RISKS

As described earlier, companies may voluntarily submit GRAS notices (which contain the GRAS safety determination) to FDA seeking the agency's agreement with their safety determination, and when they do, the agency posts these notices on its website. We reviewed the quality of the industry's notices and identified three, still under review by the FDA as of September 2013 (listed as "pending" on the FDA site), that appeared to be poorly done. They were GRN No. 466 for polyglycerol polyricinoleic acid by McCormick and Co., GRN No. 471 for annatto seed extract by DeltaGold, and GRN No. 474 for Bioperine by Sabinsa Corp.[25,26,27] All three had the same weaknesses: limited toxicology data, poor or inadequate exposure assessment, and lack of consideration of children's exposures. For each we submitted to the FDA detailed comments on the shortcomings of the safety determinations.[28] See www.nrdc.org/food/safety-loophole-for-chemicals-in-food.asp.

If the FDA rejects a GRAS notice, it explains its safety concerns in a letter to the company and publishes the letter on the agency's website. But when a company withdraws a notice and asks FDA to stop further review, the agency issues a letter confirming the withdrawal without publicly explaining any of the concerns that could have prompted the withdrawal. The withdrawal does not prevent the company from continuing to market the product for use in food.

Between 1998 and the end of February 2014, the FDA rejected 17 out of 466 notices submitted to the agency; another 32 are still pending. During that time, 80 notices were withdrawn by the companies. For notices no longer pending, one out of five were either withdrawn or rejected.[29]

After analyzing the poor quality of notices and the number of withdrawn notices, NRDC filed a FOIA request for communications between the FDA and manufacturers for 20 GRAS notifications. We chose notices for chemicals whose use in food we were able to document through a commercial database[30] that provides product information for more than 200,000 food products; and the notices were submitted throughout the length of the program, starting in 1998. Sixteen of these notices were withdrawn, several of them multiple times. Although interested primarily in understanding what concerns raised by FDA prompted manufacturers to ask the agency to stop reviewing the notices, we also included two notices that the agency rejected and two that FDA accepted as sufficient, issuing what is known as a "no questions" letter. To see the FDA's FOIA response, go to www.nrdc.org/food/safety-loophole-for-chemicals-in-food.asp.

The FOIA documents reveal that the FDA does carefully review the notifications and asks tough questions. The agency's reviews often raise serious safety concerns or reveal that the company's scientific analysis is flawed or inconsistent with the law. Often the FDA tells the company that it will reject a notice if it is not voluntarily withdrawn. If rejected, food manufacturers would be more reluctant to buy the product since FDA posts its rejection letter and its reasoning on its website.

The following are examples of four withdrawn GRAS notices and our summary of the back-and-forth communications between the FDA and manufacturers. Despite the safety concerns, these chemicals have been listed as an ingredient in some food products:

Epigallocatechin-3-gallate (EGCG):

A Japanese company declared this chemical to be GRAS for use in beverages including teas, sport drinks, and juices, despite evidence it may cause leukemia in fetuses based on studies using newborn and adult human cells grown on a dish.[31] Moreover, the company did not address a short-term study on rats showing it affected the thyroid, testis, spleen, pituitary, liver, and gastrointestinal tract. The notice did not explain potentially dangerous interactions with sodium nitrite, a common preservative, or with acetaminophen (the active ingredient in Tylenol® and many other over the counter pain-killers).[32] The company withdrew the notice, resubmitted it, but withdrew that one as well.[33] In response to our inquiries, the company assured us it was not marketing the product in the United States. However, two other companies, DSM and Kemin, appear to market chemicals high in EGCG in the United States pursuant to undisclosed GRAS determinations (Table 1). We identified more than 25 food products with EGCG as a named ingredient.

Gamma-amino butyric acid (GABA):

A Japanese company declared this neurotransmitter to be GRAS for use in beverages, chewing gum, coffee, tea, and candy.[34] It did so despite having estimated exposure well in excess of what the company considered safe, relying on unpublished safety studies, providing the specifications in Japanese, and failing to consider existing exposures.[35] The company told NRDC that it withdrew the notice "from a business perspective" and was selling the product in the United States only as an ingredient in a dietary supplement. It also indicated that it would not use the chemical in food without an FDA final review. We identified five food products with GABA as a named ingredient. These products included bottled tea and nutrition bars.

Sweet lupin protein, fiber, and flour:

An Australian firm declared these chemicals to be GRAS for use in baked goods, dairy products, gelatin, meats, and candy, despite concerns that the chemicals would cause allergic reactions in those with peanut allergies.[36] The FDA noted that a warning label for sweet lupin would be insufficient to alert consumers who suffered from peanut allergies.[37] The company did not respond to our inquiries and we could not find evidence that the company was marketing the product in the U.S. However, sweet lupin was a listed ingredient in more than 20 food products, none of which appear to bear any warning to those allergic to peanuts.

Theobromine:

A U.S. firm declared it to be GRAS for use in bread, cereal, beverages, chewing gum, tea, soy milk, gelatin, candy, and yogurt and fruit smoothies, despite having an estimated consumption rate more than five times the safe consumption level reported by the company's consultant.[38] In addition, the manufacturer did not provide convincing explanations for the testicular degeneration in rats and rabbits and delayed bone formation in rats that were seen in animal studies of theobromine.[39] The FDA was especially concerned that the product would be used in baby food.[40] The company did not respond to our inquiries. Although we don't know the provider, theobromine was a named ingredient in more than 20 food products, including isotonic waters, nutrition bars, and diet foods. Fortunately, from what we could tell, none appeared in baby food.

The evidence from these FOIA responses makes it clear: the FDA's review adds value, and many companies' GRAS safety determinations are seriously flawed. The agency should make its concerns publicly available when companies withdraw their notices. Chemicals that, at least in some instances, prompted the FDA to raise safety concerns are used as ingredients in our food supply, and consumers are unprotected from their health effects.

Table 2: Companies with undisclosed GRAS determinations that did not respond to NRDC*

Company	Country	No. of Chemicals
ADM	USA	1
AHD International	USA	1
Ametis JSC	Russia	1
Applied Food Sciences	USA	2
CBC Group	USA	1
Davos Life Sciences	Singapore	1
FutureCeuticals	USA	1
Gencor Pacific	USA	1
Hamari Chemicals	Japan	1
Hanzhong TRG Biotech	China	32
Horizon Science	USA	1
Kyowa Hakko	USA	2
Laurus Labs	India	1
Naturex	Canada	4
Nexira	France	1
NutraMax	China	154
Oxis International	USA	1
Skyherb	China	7
Terry Laboratories	USA	1
Triarco Industries	USA	2
Ventria Bioscience	USA	2
Totals	21 companies	218 chemicals

*In each case, we confirmed that we had either a: 1) confirmation from the company's website that the webform was accepted; or 2) valid email address from website because we did not get a notice from the company's email server that the email had bounced or was not deliverable.

MANY GRAS CHEMICALS BEGAN AS DIETARY SUPPLEMENT INGREDIENTS

Most of the GRAS chemicals NRDC examined were primarily marketed as "active" ingredients in dietary supplements. The availability of the GRAS loophole allows for the expansion of the market for such into conventional foods with claims that they made food "better for you." The chemicals were often extracts of plants or highly purified or synthetic versions of the biologically active chemicals in those extracts, such as antioxidants, which were purported to have possible health benefits.

Since the Dietary Supplement Health and Education Act of 1994[41], when Congress created separate, less rigorous safety standards for dietary supplements under DSHEA, there has been an explosion of these products. Ingredients allowed in dietary supplements are not necessarily safe when used in conventional food.

A product may be a natural extract or a highly purified version of one, but that does not necessarily mean it is safe. In 2014, the FDA recognized the safety threat when it issued guidance regarding substances added to foods, including beverages and dietary supplements.[42] The agency stated:

> *"We have seen a growth in the marketplace of beverages and other conventional foods that contain novel substances, such as added botanical ingredients or their extracts. Some of these substances have not previously been used in conventional foods and may be unapproved food additives. Other substances that have been present in the food supply for many years are now being added to beverages and other conventional foods at levels in excess of their traditional use levels, or in new beverages or other conventional foods. This trend raises questions regarding whether these new uses are unapproved food additive uses."*[43]

It is likely that had the FDA reviewed the undisclosed GRAS determinations, it would have found some to be unapproved food additives.

THE SYSTEM IS BROKEN AND PLAGUED WITH CONFLICTS OF INTEREST

When the FDA reviewed GRAS determinations made by manufacturers, the agency found flaws with one in five, based on the number of notices rejected or withdrawn prior to a final decision.[44] These notices presumably were those in which the manufacturer's had the most confidence, since the manufacturers voluntarily submitted them for agency scrutiny.

Food manufacturers are ultimately responsible for the safety of the food they make. However, in today's highly competitive global marketplace, there are strong economic incentives to minimize expenditures, which may lead to insufficiently-justified decisions. Our understanding of the health effects of many of the more than 10,000 chemicals allowed in food is far from complete, and as the number grows over time, concerns grow as well. For example, some manufacturers still consider *trans* fats to be GRAS despite the FDA's concluding that it causes eight deaths a day in the United States and that if it were banned from food, our country would realize more than $117 billion in health benefits including reduced healthcare costs over 20 years.[45]

Here is another issue of serious concern. For years, companies have used their own employees or hired consultants to evaluate their chemicals' safety and then relied on such undisclosed safety determinations to market their products for use in food. This raises serious conflict-of-interest concerns because a company's financial benefit from selling a particular product can bias its employees' or contractors' judgment.[46] The lack of independent review in GRAS determinations compromises the integrity of the process and calls into question whether it can effectively ensure the safety of the food supply.[47]

The FDA has acknowledged that a company's potential legal liability and its interest in protecting its brand are insufficient to ensure that food is safe.[48] In 2013 the agency said, "Because the demand for many manufactured or processed foods may not be sufficiently affected by safety considerations, incentives to invest in safety measures from farm to fork is diminished. Consequently, the market may not provide the incentives necessary for optimal food safety."[49]

"Even in cases where consumers are aware that their illness was contracted from a specific food," the FDA explained, "it is often difficult to determine who is ultimately responsible for their illness, since the particular source of contamination is not known in many circumstances."[50] It concluded that "it is unlikely that the existence of brands in the food sector creates the optimal level of safety for society."[51]

As the Institute of Medicine explained in the context of medical safety, conflicts of interest can result in bad decisions.[52] Similarly, undisclosed safety determinations affecting the food that Americans eat may be undermining public health. Without FDA and public scrutiny—as Congress intended that there be—we cannot be confident in the safety of chemicals added to food.

CONCLUSIONS

A chemical additive cannot be "generally recognized as safe" if its identity, chemical composition, and safety determination are not publicly disclosed. Congress never intended that almost all new food chemicals would pass through the GRAS loophole without formal agency review and approval. The law places responsibility on FDA to ensure that food additive petitions are submitted for additives without general recognition of safety and to ensure that manufacturers' GRAS determinations are properly made. If the FDA does not know the identity of these chemicals and does not have documentation showing that their uses in food are safe, it cannot not do its job.

In an increasingly global marketplace where many additives and foods are imported into the United States, this loophole presents an unsettling situation that undermines public confidence in the safety of food and calls into question whether the FDA is performing its duty to protect public health. Until conflicts of interest are minimized and safety decisions are subject to mandatory FDA review, the safety of chemicals in food will depend largely on the integrity and competence of food manufacturers. That is not in the public's best interest, because manufacturers have a financial incentive that may bias their judgment about an additive's safety.

When consumers buy dietary supplements, they make a choice to consume chemicals that the FDA has not reviewed for safety. Indeed, under the law, consumers must be told that FDA has not reviewed the health claims made for ingredients in dietary supplements. As a result, dietary supplements carry labels disclosing that they have not been reviewed for safety by the FDA. However, when buying food, consumers can't make informed choices because they don't know which ones contain reviewed chemicals or which contain substances not reviewed by the FDA for safety. There are no warning labels. There is no disclosure. As a consequence, they may unknowingly be putting their health at risk. The current processes allowing this to occur should be addressed and changed to better protect the health of the American public.

NRDC'S RECOMMENDATIONS

The problems identified in this report are rooted in a law adopted more than a half century ago. Ultimately, Congress needs to fix these problems. Until it does, the FDA should implement the recommendations made by the GAO in 2010 including strictly limiting conflicts of interests and requiring that the FDA be informed of GRAS determinations so it can confirm that the chemical's use in food is generally recognized as safe. The agency should also make its concerns with all notices it reviews, even those that are withdrawn, publicly available.

In the meantime, consumers should demand that their grocery stores and their favorite brands sell only food products with ingredients that the FDA has found safe, and call on the FDA and Congress to make the necessary changes to better ensure that food consumed in the U.S. is safe.

ENDNOTES

1 Thomas G. Neltner et al., "Navigating the U.S. Food Additive Regulatory Program," *Comprehensive Reviews in Food Science and Food Safety* 10 (2011), p. 342.

2 NRDC, Main FDA Response to FOIA, 2014, p. 210, www.nrdc.org/food/files/chemicals-in-food-FOIA-Main.pdf regarding GRN No. 257.

3 21 U.S.C. § 321(s) and § 348.

4 Pub. L. No. 85-929, 72 Stat. 1784 (1958).

5 21 C.F.R. § 170.3(i).

6 21 U.S.C. § 348. Fred H. Degnan, *FDA's Creative Application of the Law*, Food Drug Law Institute, 2000, p. 25.

7 Degnan, p. 22.

8 Neltner, "Navigating," p. 342.

9 NRDC, GRN No. 59 FDA Response to FOIA, 2014, p. 271, www.nrdc.org/food/files/chemicals-in-food-FOIA-59.pdf.

10 21 U.S.C. §§ 321(s), 348(a).

11 21 C.F.R. § 170.30. Neltner, "Navigating," p. 347.

12 Ibid.

13 Ibid. Unlike individual food manufacturers, since 1963 the flavor industry has publicly identified its chemicals and their allowed uses for those it found to be GRAS. It also submitted its safety documentation to the agency. See Flavor and Extract Manufacturers Association, *About the FEMA GRAS Program*, www.femaflavor.org/gras (accessed March 4, 2014).

14 21 C.F.R. § 170.35.

15 Neltner, "Navigating," p. 347; Linda S. Kahl to Docket No. FDA-1997-N-0020, *Substances That Are Generally Recognized as Safe (GRAS); Experience with GRAS Notices* (Nov. 4, 2010), p. 26. Degnan, p. 32.

16 62 Fed. Reg. 18,938, 18,939 (April 17, 1997). See also Neltner, "Navigating," p. 360.

17 FDA, Guidance for Industry: Frequently Asked Questions About GRAS, www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm061846.htm (accessed January 8, 2014).

18 In February 2014, the Center for Food Safety sued the FDA to finalize the proposed rule. See Center for Food Safety, *Illegal "Fast-Track" Puts Americans at Risk for More than Fifteen Years,* www.centerforfoodsafety.org/press-releases/2924/center-for-food-safety-sues-fda-over-food-additives (accessed March 4, 2014).

19 Government Accountability Office, *Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)*, 2010, p. 8, 20, www.gao.gov/products/GAO-10-246.

20 American Institute for Biosocial and Medical Research, GRAS Self-determination Inventory Database, www.aibmr.com/resources/GRAS-database.php (accessed November 15, 2013).

21 FDA, GRAS Notice Inventory, www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices (accessed November 15, 2013).

22 Magnuson B et al., "Review of the regulation and safety assessment of food substances in various countries and jurisdictions," *Food Additives & Contaminants: Part A.* 2013. DOI: 10.1080/19440049.2013.795293

23 NRDC, Main FDA Response to FOIA, 2014, p. 207, www.nrdc.org/food/files/chemicals-in-food-FOIA-Main.pdf regarding GRN No. 257.

24 Kahl, p. 5.

25 FDA, GRAS Notice Inventory, GRN No. 466. www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices. The FDA issued a "no questions" letter before the NRDC submitted its comments.

26 Ibid, GRN No. 471. It was pending as of February 28, 2014.

27 Ibid, GRN No. 474. It was withdrawn before the NRDC submitted its comments.

28 NRDC, Comments on GRN No. 466, 2013, www.nrdc.org/food/files/chemicals-in-food-GRN-466.pdf and NRDC, Comments on GRN No. 471, 2013, www.nrdc.org/food/files/chemicals-in-food-GRN-471.pdf and NRDC, Comments on GRN No. 474, 2013, www.nrdc.org/food/files/chemicals-in-food-GRN-474.pdf.

29 As of February 28, 2014, the FDA's website listed 498 notices with 32 pending, 80 withdrawn, and 17 rejected because they had an insufficient basis to determine the chemical was GRAS. 20.8% = (80+17)/(498-32)*100%.

30 See www.gladson.com. March 15, 2013 version

31 FDA, GRAS Notice Inventory, GRN No. 225 and NRDC, Main FDA Response to FOIA, 2014, p. 197, www.nrdc.org/food/files/chemicals-in-food-FOIA-Main.pdf regarding GRN No. 225.

32 Ibid.

33 FDA, GRAS Notice Inventory, GRN No. 259.

34 FDA, GRAS Notice Inventory, GRN No. 257.

35 NRDC, Main FDA Response to FOIA, 2014, p. 206, www.nrdc.org/food/files/chemicals-in-food-FOIA-Main.pdf.

36 FDA, GRAS Notice Inventory, GRN Nos. 262, 263, and 264 and NRDC, Main FDA Response to FOIA, 2014, p. 218, www.nrdc.org/food/files/chemicals-in-food-FOIA-Main.pdf.

37 *Ibid.*

38 FDA, GRAS Notice Inventory, GRN No. 340 and NRDC, Main FDA Response to FOIA, 2014, p. 223, www.nrdc.org/food/files/chemicals-in-food-FOIA-340.pdf.

39 Ibid, p. 223.

40 Ibid, p. 219.

41 Pub. L. No. 103-417, 108 Stat. 4325 (1994).

42 FDA, *Guidance to Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements,* 2014. See www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/UCM381316.pdf.

43 Ibid.

44 Neltner, "Navigating," p. 347. See Note 28.

45 78 FedReg 67169, November 8, 2013.

46 Thomas G. Neltner et al., "Conflicts of Interest in Approvals of Additives to Food Determined to be Generally Recognized as Safe: Out of Balance," *Journal of American Medical Association–Internal Medicine*, August 2013, E2, DOI:10.1001/jamainternmed.2013.10559.

47 Ibid.

48 FDA, *Preliminary Regulatory Impact Analysis for the Proposed Rules for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food,* Docket No. FDA-2011-N-0920, p. 2-3. See www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334117.pdf.

49 Ibid., p. 2.

50 Ibid., p. 3.

51 Ibid.

52 Bernard Lo and Marilyn J. Field, eds., *Conflict of Interest in Medical Research, Education, and Practice* (Washington, D.C.: National Academies Press, 2009).

Support for this project was provided by The Pew Charitable Trusts. The views expressed herein are those of the author(s) and do not necessarily reflect the views of The Pew Charitable Trusts.

Natural Resources Defense Council
40 West 20th Street
New York, NY 10011
212 727-2700
Fax 212 727-1773

Beijing

Chicago

Los Angeles

Bozeman

San Francisco

Washington, D.C.

www.nrdc.org

www.nrdc.org/policy
www.facebook.com/nrdc.org
www.twitter.com/nrdc

Printed on recycled paper

Attachment 29

The Washington Post

Federal Insider

Are secret, dangerous ingredients in your food?

By Kimberly Kindy April 7, 2014

Food manufacturers are routinely exploiting a “legal loophole” that allows them to use new chemicals in their products, based on their own safety studies, without ever notifying the Food and Drug Administration, according to a new report by an environmental and consumer advocacy group.

Natural Resources Defense Council identified 56 companies that were marketing products using 275 chemicals that the company’s hired experts decided met federal safety standards, known as Generally Recognized as Safe (GRAS). However, the science behind those safety findings and the use of the chemicals was disclosed to the FDA in only six instances. The New York-based NRDC called its report “Generally Recognized as Secret” and said the lack of transparency with the GRAS process is a public health threat.

“If you don’t know when (an additive) is being used, how can you determine if it’s safe?” said Thomas Neltner, a chemical engineer and co-author of the study that was presented Monday at a Grocery Manufacturers Association’s Science Forum at Washington.

In a prepared statement, the GMA defended the GRAS process, saying, “It is a very thorough and comprehensive process that has, under the current law provided FDA with authority to challenge the improper marketing of an ingredient as GRAS, and if necessary, act to remove products containing that ingredient from the food supply.”

The FDA said that although the law allows for food manufacturers to make their own safety determinations, the agency “encourages companies to consult with the agency when developing new ingredients.” Ultimately, the FDA said, manufacturers “are responsible for ensuring that their food products are safe and lawful.”

NRDC said that Food Additives Amendment of 1958 was enacted, the GRAS process was meant to apply to innocuous additives like vinegar. Instead, it is commonly used for chemicals that are potentially dangerous and have never before been in the American food supply. For example, until recently, artificial transfats were considered GRAS but the FDA has now deemed them dangerous, saying they cause as many as 7,000 deaths from heart disease each year.

The organization said its findings are “likely the tip of the iceberg,” since the scientific work and GRAS determinations are not publicly disclosed and therefore difficult to track down. The organization spent more than a year reviewing trade journals and talking to food additive consultants to identify the 56 companies that frequently make their own safety determinations.

The FDA’s food additive process allows companies to take several paths to determine the safety of new chemicals or other ingredients.

The most transparent and rigorous path involves companies submitting a food additive petition – along with the science behind why they think the ingredient is safe — to the FDA in an effort to gain formal approval from the agency. Companies use the FDA approvals to promote the safety of their products.

The other, non-public path that NRDC examined allows companies to determine GRAS status on their own without notifying the FDA.

A third path allows companies to voluntarily submit their own GRAS determinations for FDA review and sign off, but they may withdraw the petition if the agency is worried about the safety of the additive. The agency announces the withdrawal but does not disclose whether it had safety concerns. The company may then go ahead and use its own GRAS determination to use the additive in products anyway. The NRDC found that one in every five GRAS petitions were either rejected by the FDA or the company voluntarily withdrew their petition.

NRDC’s report also calls on the FDA to petition Congress for a new law that would require manufacturers to submit their safety determinations to the agency for review and approval. The council said it is encouraging consumers to “demand” that their grocery stores and their favorite brands sell only food products with ingredients that the FDA has found to be safe.

At Monday’s event, the Grocery Manufacturers Association also announced a new food additive research center it has helped create at Michigan State University, which will be called the Center for Research on Ingredient Safety (CRIS). GMA’s chief science officer, Leon Bruner, said the center will operate independent of the association and will review the safety of ingredients, train future food toxicologists and serve as an “independent and credible source” for the public, news organizations and the industry.

Kimberly Kindy is a national investigative reporter at The Washington Post. Follow @kimberlykindy

---

Attachment 30

E&E NEWS

BRISTOL BAY

'Homework assignment' — how Pebble lobbied Trump's EPA

Kevin Bogardus and Dylan Brown, E&E News reporters

Greenwire: Thursday, June 8, 2017

The backers of the controversial Pebble mine planned for Alaska's Bristol Bay lobbied U.S. EPA to reverse its decision on the mining project. Robert Glenn Ketchum/Natural Resources Defense Council

Developers of a controversial Alaskan mine set out early to lobby President Trump's U.S. EPA to reverse restrictions the Obama administration had proposed putting on the project.

Peter Robertson, a top lobbyist for Pebble LP — the developer of the Pebble mine in Bristol Bay, Alaska — emailed and met with a senior EPA official to discuss the project, according to records released in response to a Freedom of Information Act request by the Natural Resources Defense Council. The documents illuminate that the latest push in Pebble's decadelong lobbying campaign bore fruit, as the company and EPA reached a deal last month to allow the project to enter permitting.

Two days before the Senate confirmed Scott Pruitt as EPA administrator in February, Robertson — who also served as EPA chief of staff under then-agency head Carol Browner during the Clinton administration — reached out to David Schnare at EPA, asking to meet in person to discuss the mining project.

Robertson **said in an email** that EPA's effort, through its Pacific Northwest Region 10 office, that effectively blocked the mine was "unprecedented and fundamentally unfair."

In 2014, Region 10, which oversees Alaska, proposed Clean Water Act restrictions on large-scale mining in Bristol Bay (***Greenwire***, May 17). Alaska Native groups, conservationists and the commercial fishing industry praised EPA for protecting the region's world-renowned salmon fishery.

Peter Robertson EPA Alumni

"We are only looking for the same due process that 60,000 other permit applicants get each year," Robertson said, noting that "there is a significantly long history of this matter (including our litigation against the Agency), and I would appreciate the opportunity to discuss it with you and seek your guidance and assistance on our efforts to work through these issues with the Agency.

"Do you have time for me to meet with you in the near future?" Robertson asked.

Schnare **responded** the next day, saying he was open to meeting with the Pebble mine lobbyist.

"I am aware of the problem in general but do not have specifics. Can you bring with you a timeline of events and a status on the legal actions? The preemptive strike by the last administration was indeed unprecedented and I don't want to see it become a precedent, particularly because it is a violation of Pebble's due process rights," Schnare said.

"In any case, I need to get this set up for the Administrator, which means I need the full background and a specific proposal on what we can and should do. Without meaning to be flip,

that's your homework assignment," Schnare added.

The two then arranged to meet in person the following week, according to the emails. A day after the Feb. 22 meeting date, Robertson **emailed** Schnare to thank him and pass on several websites and documents — including a **letter** from House Science, Space and Technology Chairman Lamar Smith (R-Texas) asking EPA to let the mining project move forward.

"If you have questions after speaking with Region 10, I would really appreciate the opportunity to respond to them," Robertson said.

The next week, Robertson again emailed Schnare, passing along a **letter** from Pebble to Rep. Eddie Bernice Johnson (D-Texas), the Science panel's ranking member, taking issue with the congresswoman's criticism of the project (***Greenwire***, Feb. 27).

"What I really wanted to talk about though, is the substance of it," Robertson **said**.

'Tip of the FOIA iceberg'

A Region 10 official said EPA headquarters would be declining to comment on this story.

In an email responding to questions about Pebble's lobbying of EPA, Robertson said: "We have met with a range of people at EPA — during this administration and the prior administration — to discuss the many problems with their precedent-setting preemptive actions against us.

"Our efforts have been targeted towards ensuring that EPA's leaders are well informed about all relevant issues regarding our project. Discussions regarding settlement, as you would expect, have largely been handled by our lawyers."

Taryn Kiekow Heimer, a senior policy analyst at NRDC who requested the records via FOIA, criticized Pebble's discussions with EPA over the mining project, calling it "a shameless giveaway to industry" to let the permitting process move forward.

"After years of belly-aching about fairness, it is simply unbelievable that Pebble immediately seized the opportunity to reach a secretive, backroom deal with the Trump EPA," she said in an email. "Trump's EPA went from not knowing any 'specifics' about the mine to cutting a deal with Pebble that greenlights the mine into permitting."

Schnare, the EPA official who met with Robertson, was a member of Trump's transition team and later the "beachhead" team for the agency. He had previously spent 33 years at EPA, including working as an attorney in the agency's enforcement office, before returning to EPA this year.

At the Energy and Environment Legal Institute, Schnare was a vocal critic of EPA under the Obama administration. He expected to stay on at EPA in a top position but resigned from the agency by mid-March after he made allegations of wrongdoing (***Greenwire***, March 16).

In an interview with E&E News, Schnare remembered meeting with Robertson and discussing the mining project with other EPA beachhead team members.

Schnare said after he was briefed by Pebble, he sought and received a briefing from EPA staff. Then, Schnare said, he took the information to Pruitt

"I never gave anything to Pruitt. I did brief him," Schnare said.

Schnare said he wanted to make sure that all sides and arguments surrounding the issue were known within EPA.

"There was nothing offered up by Peter Robertson that the agency didn't already know," Schnare said. "My approach has been to hear from both sides."

Schnare also said "there was this whole precedence issue" with the Pebble mine.

"Do you kill a project without due process?" Schnare said. "Due process is something the public deserves."

NRDC's Kiekow Heimer questioned EPA's decisionmaking process that led to the settlement, saying the agency lacked "a balanced perspective since there was no effort, as far as I know, to reach out to any of the stakeholders except Pebble."

More information may be forthcoming on Pebble's lobbying campaign directed at Trump's EPA. Kiekow Heimer said she expected the agency to produce two more rounds of documents in response to her request.

"This is just the tip of the FOIA iceberg," she said.

Twitter: **@KevinBogardus** | Email: **kbogardus@eenews.net**